

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

THE WASHINGTON UNIVERSITY, )  
                                )  
Plaintiff,                 )  
                                )  
v.                            ) C.A. No. 13-2091 (JFB)  
                                )  
WISCONSIN ALUMNI RESEARCH ) Public Version  
FOUNDATION,                 )  
                                ) Filed 4/24/18  
                                )  
Defendant.                 )

**WARF'S PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW**

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## **CITATION FORMS, ABBREVIATIONS, AND WITNESS TESTIMONY**

### Explanation of Citation Forms

COL	A paragraph in WARF's Proposed Conclusions of Law
FOF	A paragraph in WARF's Proposed Findings of Fact
Tr.	Citation to trial transcript (Tr. omitted if witness name is provided)
UF	A paragraph in the parties' statement of uncontested facts [D.I. 154, Exhibit 1 of Proposed Joint Pretrial Order]
Dep. Tr.	Citation to deposition transcript lodged by WashU on behalf of the parties in D.I. 163
Bold and/or italicized word	Unless otherwise indicated, emphasis was added for any bold or italicized word

### Abbreviations

WARF	Wisconsin Alumni Research Foundation
WashU	The Washington University
Abbott	Abbott Laboratories
IIA or 1995 IIA	Inter-institutional Agreement (JX1)
'497 compound patent	U.S. Patent No. 5,587,497 (JX3)
'925 controlling use patent	U.S. Patent No. 5,246,925 (JX2)
1993 WARF-Abbott License	License between WARF and Abbott effective January 1, 1993 (JX5)
1998 WARF-Abbott License	License between WARF and Abbott effective July 28, 1998 (JX8)
USPTO	United States Patent and Trademark Office

'815 patent	U.S. Patent No. 5,597,815 (JX4)
FDA	U.S. Food and Drug Administration
Orange Book	FDA publication entitled “Approved Drug Products with Therapeutic Equivalence Evaluations”
2001 Letter or April 2001 Letter	WARF’s April 2001 letter to WashU (JX49)
AUTM	Association of University Technology Managers

Citations to Live Trial Testimony (in order of testimony at trial)

Cleare	Plaintiff's expert Dr. Michael Cleare (Trial Day 1, pp. 165-335)
Surber	Plaintiff's witness James Surber (Trial Day 2, pp. 393-485)
Thomas	Plaintiff's expert Vincent Alexander Thomas (Trial Day 2, pp. 520-621)
Gulbrandsen	WARF's witness Carl Gulbrandsen (Trial Days 2 and 3, pp. 623-680, 688-750)  A picture of Dr. Gulbrandsen is included in Exhibit A
Lentz	WARF's expert Edward Lentz (Trial Day 3, pp. 775-915)  A picture of Mr. Lentz is included in Exhibit A
Severson	WARF's expert James Severson (Trial Day 3, pp. 915-1033)  A picture of Dr. Severson is included in Exhibit A
Mulhern	WARF's expert Carla Mulhern (Trial Day 4, pp. 1059-1128)  A picture of Ms. Mulhern is included in Exhibit A

Citations to Deposition Trial Testimony

Slatopolsky	Dr. Eduardo Slatopolsky, WashU (Deposition testimony played during Trial Day 1, pp. 118-143)
DeLuca	Dr. Hector DeLuca, University of Wisconsin (Deposition testimony played during Trial Days 1 and 3, pp. 144-164, 760-775)
Brandt	Dr. E.J. Brandt, WashU (Deposition testimony played during Trial Days 2 and 4, pp. 343-372, 1040-1049)
Kratochvil	Jon Kratochvil, WashU (Deposition testimony played during Trial Days 2 and 4, pp. 372-392, 1049-1054)
Stoveken	Mark Stoveken, WARF (Deposition testimony played during Trial Day 2, pp. 486-519)

## **WARF'S POST-TRIAL PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW**

This matter was tried before the Court from March 26, 2018, through March 29, 2018.

Pursuant to the Court's Order, WARF submits proposed findings of fact and conclusions of law, which are separately set forth in accordance with Fed. R. Civ. P. 52(a).<sup>1</sup>

### **INTRODUCTION**

1. This is a breach-of-contract case where WashU looks back with 20-20 hindsight at a twenty-year-old agreement and now contends, based on unforeseen actions by Abbott, that the original agreement was unfair and WashU is entitled to more money. But WashU has failed to actually say what the alleged breach was in the first place or what WARF should have done differently.

2. Is the alleged breach that WARF should have assigned a different relative value to the '815 patent in 1998? Or is it that WARF should have revisited the original assignment of relative value based on a "major event"? The evidence at trial established there was no breach—express or implied—under either theory. There was no self-dealing or unfairness by WARF. WashU agreed with WARF's actions, at least until WashU's in-house lawyer James Surber got involved in 2012. By then, WashU's change in course was too late. WashU's claims, which are based on WARF's assignment of relative value in 1998, are time-barred under Wisconsin's six-year statute of limitations.

3. The parties agree that the terms of the IIA are clear and unambiguous. WARF had the authority to assign a relative value upon licensing the '815 patent as part of the larger portfolio. The trial record established that WARF assigned a fair relative value in accordance

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<sup>1</sup> To the extent any of the findings of fact set forth below is a conclusion of law, or a conclusion of law is a finding of fact, the substance of each statement rather than its form or characterization shall control.

with WARF's decades-long practices in patenting, licensing, and assigning relative values to patents within Dr. Hector DeLuca's larger Vitamin D portfolios. WARF has patented hundreds of Dr. DeLuca's inventions and licensed dozens of large Vitamin D patent portfolios, always assigning a majority of the relative value to the most important patent in any pharmaceutical portfolio—the compound patent. This is standard practice because WARF, like WashU (and other universities), does not have the manpower or the expertise to conduct claim-by-claim infringement analyses for every licensed patent in a large portfolio. But this practice is now being questioned by WARF's supposed failure to look into a crystal ball in 1998 and see that Abbott would list the '815 patent in the Orange Book thirteen years after it was required by the FDA to do so.

4. WashU argued at trial that the '815 patent was extremely important. To determine whether WashU has been treated fairly, the relevant analysis necessarily must involve consideration of the '815 patent's importance to Abbott—the licensee—and the manner in which the '815 patent was used as a blocking patent to protect against generic entry. But the evidence showed that Abbott did not use the '815 patent for more than thirteen years to protect against generic entry. The evidence also showed that while Abbott was offered a license in 1996, it did not take a license to the '815 patent until July 1998, after the FDA approved and Abbott started selling Zemplar® for the treatment of secondary hyperparathyroidism in patients with chronic kidney disease. Even then, Abbott paid WARF nothing additional to take a nonexclusive license to the '815 patent. Abbott never asked for an exclusive license in 1998, and Abbott did not list the '815 patent in the Orange Book in 1998, mark it on its Zemplar label, or assert it in the two most important generic litigations against the first-to-file generic companies in 2008 (Teva) and 2009 (Sandoz). After the FDA rejected Abbott's proposed indication of treatment for renal

osteodystrophy while avoiding hyperphosphatemia—the method of use claimed in the '815 patent—Abbott never pursued approval of that indication.

5. WashU also fails to identify what WARF should have done if it didn't follow its standard practice in assigning relative values. Even its own expert Vincent Thomas presented a range of uncertain relative value percentages from which he could not pick one. But the evidence showed that, over the life of the '815 patent, WARF's original valuation and compensation paid to WashU was fair. In particular, that was shown by the incremental income attributable to the '815 patent over the entire term of the license agreement.

6. WashU further argues that WARF treated WashU "shabbily." While the evidence at trial proved WashU's allegation false, WARF's treatment of WashU was not a breach of the IIA.

7. In fact, WashU's entire case for breach is predicated primarily on the clearly erroneous (and unspoken) assumption that WARF should have known in 1998 when it set the relative value under the terms of the IIA about Abbott's late listing of the '815 patent in the Orange Book in 2011. And when that theory comes up short, WashU falls back on a supposed duty to revalue based on fairness. But on this issue—the parties' intent to revisit the valuation—the evidence is conclusive. The terms of the IIA are completely silent on re-evaluation, as is any other evidence of the parties' intent, such as the 1995 letters between the parties leading up to the IIA. Dr. Brandt, who negotiated and signed the IIA for WashU, did not remember the IIA, WARF, Mr. Bremer, or the negotiations at all.

8. And further to the parties' intent in 1995, there is no excuse that, even as a junior party, WashU did not keep copies of the agreement or correspondence or otherwise maintain its files. Nor did it conduct any due diligence or review any information about the Zemplar market,

the '815 patent, or Zemplar's Orange Book listings until 2012. And WashU's allegation of a customary practice of re-evaluating relative values within a patent portfolio is a litigation-driven scenario. This is shown by the simple fact that WashU's expert Dr. Michael Cleare had no evidence in either industry articles, discussions, or surveys that suggested revisiting relative value was a common practice based on some unforeseen change in circumstances. Nor could he identify when and under what circumstances would it be customary for a university technology transfer office to revisit relative value absent some express provision in an inter-institutional agreement to do so.

9. By 2001, it is undisputed that WashU knew (or at least should have known) that:

- WARF had licensed the '815 patent to Abbott as part of a pre-existing portfolio.
- WARF assigned the '815 patent to the Ancillary Patent group with 30 other WARF-owned patents.
- WARF placed a significantly higher relative value (70 percent) on the '497 compound patent family.
- As part of the Ancillary Patent group, the '815 patent shared *equal* relative value (0.968 percent) with the other 30 Ancillary Patents.
- Abbott's total sales of Zemplar.
- The total royalties WARF received from Abbott.
- WashU's own Dr. Slatopolsky had entered into a sponsored research agreement with Abbott and was conducting biological testing on paricalcitol as early as 1993.
- The '815 patent was a later-filed method-of-use patent covering a method of treating a patient having renal osteodystrophy.
- Abbott did *not* list the '815 patent in the Orange Book upon FDA approval, but instead listed the patents that drove commercialization of Zemplar, including the compound patent (the '497 patent), the controlling method-of-use patent (the '925 patent), and two Abbott-owned formulation patents.

- The 1995 IIA did not contain any “milestones” or any other later-occurring market events (like Abbott’s listing of the ’815 patent in the Orange Book) related to a licensee’s (in this case, Abbott’s) use of the ’815 patent that would require WARF to reallocate its relative value in the licensed portfolio.

If WashU disagreed with WARF’s valuation of the ’815 patent or intended for WARF to revisit the assigned relative value every year or upon major events, why did WashU not write or say anything to WARF for over twelve years?

10. To try to seek damages back to 1998, WashU’s case is premised on WARF’s alleged fraudulent concealment of an earlier Abbott license based on a single 1998 email. But the evidence presented at trial did not show that WARF fraudulently concealed anything. At the time of the 1998 email, the 1998 WARF-Abbott License did not exist, and there was no license to the ’815 patent to give WashU. WARF did not conceal the .968 percent relative value by telling WashU it was more, or misrepresent to WashU who was paying them royalties or for what drug, or even hide from WashU the amount of royalties WARF received. While those might be examples of fraudulent concealment, this case is just the opposite—WARF told WashU all of this, and truthfully. It is not WARF’s fault that WashU did not ask for any additional information after 2001 and before 2012, and it certainly cannot be WARF’s fault that Abbott listed the ’815 patent in the Orange Book in 2011.

11. Should WashU somehow get past the statute of limitations, which should be fatal to its case, there was still no express breach of the IIA, and the implied covenant of good faith and fair dealing “does not provide an independent source of obligations from which a court may draw to reform agreements because they appear with the benefit of hindsight to be inequitable or unreasonable.” *Gilson v. Rainin Instrument, LLC*, No. 04-C-852-S, 2005 U.S. Dist. LEXIS 16825, at \*5 (W.D. Wis. Aug. 9, 2005). WARF should not be penalized today—no matter how unfair it may seem in hindsight—because even WashU conceded, absent Abbott’s late Orange

Book listing, there was “nothing” for WashU to do. [Kratochvil 381:20-382:9.] Holding WARF in breach today for Abbott’s actions, which WARF had no control over, would not just affect WARF and WashU. It would have far-reaching effects on university licensing in the pharmaceutical industry that neither party contemplated in 1995 or practices today.

12. The fair result in this case can only be arrived at by viewing the evidence, by considering what was said at the time, based on what was known at the time, and not by looking back in time with 20-20 hindsight. Neither party could read a crystal ball to know how Abbott was going to use the patents in the licensed portfolio. And the best evidence of that—undisputed by both parties—is that, for more than a decade, Abbott did not use the ’815 patent to protect the market from generic entry. And that is why WARF’s blended approach to spreading equal payments to each of the ancillary patents over the entire term of the Abbott License Agreement was fair in 1998 when it allocated an equal share among all ancillary patents. It also turns out that it ended up being fair today because, as the evidence showed, it was the ’497 compound patent that protected the market against generic competition and was responsible for the capped seven percent royalty from 1998 through March 2015.

### **PROPOSED FINDINGS OF FACT**

#### **I. THE 1995 INTER-INSTITUTIONAL AGREEMENT**

13. In 1995, Dr. Hector DeLuca of the University of Wisconsin and Dr. Eduardo Slatopolsky of WashU discovered that the administration of paricalcitol can also have a minimal effect on blood serum phosphorus while avoiding hyperphosphatemia (high levels of

phosphorus).<sup>2</sup> [JX4; Slatopolsky 127:11-128:15, 138:7-17; JX508.019 (Slatopolsky Dep. Tr.) at 69:19-22 (“I discovered the properties of the drug as far as hyperphosphatemia.”).]

14. Based on Dr. DeLuca’s recognition that this previously unappreciated property of paricalcitol may be patentable, WARF’s patent counsel prepared and filed the ’815 patent application on July 13, 1995. [DeLuca 771:6-20, 774:18-775:15; DeLuca Dep. Tr. 115-116, 120-121; UF ¶ 22.]

15. There was no prior agreement—written or otherwise—between Dr. DeLuca and Dr. Slatopolsky regarding their joint invention, nor was there any contractual requirement that WARF enter into an inter-institutional agreement. Without the IIA, each party would have been free to license its one-half share ownership.

16. WARF’s Howard Bremer, who by that time had decades of experience in patenting and licensing Dr. DeLuca’s Vitamin D portfolios, took the initiative, as was customary in university practice, to reach out to WashU only eight days after filing the ’815 patent application to propose that the parties enter into an inter-institutional agreement to patent, license, and commercialize the technology. [JX39.] With regard to patent filings, it was usual practice for patent counsel to work directly with the inventors, and Dr. E.J. Brandt, Director of WashU’s Office of Technology Management for the Medical School, had no problem with WARF contacting Dr. Slatopolsky directly. [Brandt 1042:2-21.]

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<sup>2</sup> The new chemical entity paricalcitol and its use in treating secondary hyperparathyroidism in chronic kidney disease while avoiding unwanted calcium effects was disclosed and claimed in an earlier patent application WARF filed on behalf of Dr. DeLuca and his Wisconsin colleagues in March 1989, six years before filing the ’815 patent application. [Gulbrandsen 642:22-643:13; DeLuca 768:1-770:10.] The single patent application filed in 1989 led to the two critically important patents, the ’497 compound patent and the ’925 controlling use patent. [Gulbrandsen 642:22-644:1, 734:18-735:9; Lentz 785:19-787:5.]

**A. The Negotiation of the 1995 IIA**

17. The parties' negotiation over the terms of the IIA lasted a few months, consisting of a few oral and written communications and an exchange of minimally revised drafts between Mr. Bremer and Dr. Brandt. [JX39; JX40; JX41; JX170; JX171.]

18. In 1995, WARF and WashU both had established and sophisticated technology transfer offices. [UF ¶¶ 2-3; Severson 935:6-24; Gulbrandsen 624:7-20, 628:21-630:12.] That year alone, WashU realized between \$100-\$200 million in revenue from grants and contracts, filed for 32 U.S. patents, and entered into more than 43 new licensing agreements. [JX264; Brandt Dep. Tr. 36:22-37:9; Surber Dep. Tr. 22:10-15.]

19. WashU was actively involved in negotiating the IIA, including the drafting process itself, and every one of its requested revisions was incorporated in the final agreement. [JX41; JX170; Brandt 1041:11-1048:15; Severson 941:12-22.]

20. Dr. Brandt signed the agreement on behalf of WashU as "an 'authorized' signatory for Washington University," after informing WARF that "it [was] not necessary for [her] to have attorney review/approval before [she] sign[ed]-off for the University." [JX41; JX1.008; Brandt 1046:6-14; Severson 940:14-941:2.]

**B. The Material Terms of the 1995 IIA**

21. Under the terms of the 1995 IIA, WashU assigned to WARF all commercial rights to the '815 patent, giving WARF authority and control to decide, execute, and manage all commercial responsibility: patenting, licensing, and litigation matters. [Brandt 1046:1-5; Severson 938:12-15; JX1.] WashU wanted, and WARF agreed that WashU could retain, the right to use the joint invention for "academic (i.e. non-commercial) research purposes" only. [JX41; JX1 § 2.B.(i); Brandt 1045:8-1046:5; Severson 937:17-938:15.]

22. With regard to information sharing between the parties, the only request made by WashU's Dr. Brandt to WARF was for an express provision [*see JX1 § 2.A.(v)*] for WARF to send to WashU "a copy of all issued patents within the scope of this Agreement naming Dr. Eduardo Slatopolsky as co-inventor." [JX41; Severson 939:21-940:9.] Dr. Brandt did not request that the 1995 IIA include any other provision obligating WARF to send WashU any other documents, including materials related to prosecution or licensing. [Cleare 274:24-275:18; Severson 930:17-931:19, 939:21-940:13.]

23. The relevant material terms of the 1995 IIA agreed on by the parties are as follows:

- "[WashU] grants to WARF the exclusive right to prepare, file, prosecute, and maintain Patent Rights and related Property Rights, and WARF shall have sole discretion to make decisions with respect thereto." [JX1 § 2.A.(i).]
- "[WashU] grants to WARF the exclusive right to negotiate, execute, administer, and enforce License Agreement(s), and WARF shall have sole discretion to make decisions with respect thereto." [Id. § 2.B.(i).]
- "WARF will have the final authority to enter into negotiations and execute License Agreement(s)." [Id. § 2.B.(iii).]
- "In licensing Patent Rights and/or Property Rights, WARF may include rights under other patents and/or other proprietary rights to which WARF owns a part of or all right[,] title[,] and interest, or include in other licenses certain Patent Rights or Property Rights, which licenses may be directed primarily to other invention subject matter or technology than that contemplated in this Agreement. In such event WARF shall have the authority to assign relative values to Patent Rights and/or Property Rights, and other patent and/or other proprietary rights as are included in any such license and the portion of the gross receipts from royalties and other fees received by WARF under any such license, which shall be Income hereunder to be divided with [WashU] as provided in Section 3A(i), shall be determined in accordance with such relative values assigned to Patent Rights and/or Property Rights in proportion to the total value represented by all patent rights and/or proprietary rights which are included within such license." [Id. § 3.A.(iii).]

- “WARF shall have the sole and exclusive right to determine whether or not the parties hereto shall engage in and prosecute any legal actions involving Patent Rights or Property Rights, including without limitation interferences, oppositions, reissues, reexaminations, or infringement or validity actions and further including appeal proceedings in any of them. Such actions shall be at WARF’s cost and shall be under the exclusive control of WARF.” [*Id.* § 9.A.]
- “Neither party to this Agreement makes any other warranties or representation of any kind unless expressly stated in writing in this agreement or in an amendment thereto signed by both parties.” [*Id.* § 4.D.]
- “It is understood, as between WARF and [WashU], that this Agreement constitutes their entire agreement, both written and oral . . . . No amendment or modification of this Agreement will be binding upon the parties unless made in writing and signed on behalf of each party.” [*Id.* § 13.]

24. In view of Dr. DeLuca’s extensive patent portfolios covering his vitamin D inventions, the 1995 IIA authorized WARF to license the parties’ joint ’815 patent as part of a larger portfolio that included other WARF-owned patents. [JX39; JX1 § 3.A.(iii).] If WARF licensed the ’815 patent as part of a larger portfolio, the 1995 IIA authorized WARF to assign a relative value to each of the licensed patents, and WashU’s share of licensing income in all future years would be governed by the assigned relative value. [JX1 § 3.A.(iii); Cleare 182:16-183:7; Severson 945:24-946:12.]

25. In Mr. Bremer’s first letter to Dr. Brandt, enclosing a draft agreement, he explained the need, importance, and flexibility required for the Relative Value Clause. [JX39; Cleare 251:24-253:3; Severson 936:19-937:16; Gulbrandsen 668:8-669:19, 670:13-671:7.] He wrote that almost all of the more than 50 licenses for Dr. DeLuca’s Vitamin D portfolios included multiple patents, and that “WARF has encountered great reluctance on behalf of its licensees to identify which of the patents included in a licensing agreement as a matter of convenience to the parties are actually being used.” [JX39.] WARF therefore needed “the

flexibility required and allowed under Section 3.A.(iii) [the Relative Value Clause of the 1995 IIA].” [JX39.]

26. WashU executed the 1995 IIA with no revisions or comments to the Relative Value Clause. [JX41; Severson 941:3-11.] Dr. Brandt testified that the Relative Value Clause was clear and “agreeable to [her].” [Brandt 349:5-350:2.]

27. Under the 1995 IIA, WashU negotiated and agreed to be paid 33 1/3 percent of the revenues from licensing the ’815 patent (after deducting certain patent expenses), with WARF to keep the remaining 66 2/3 percent. [JX1 § 3.A.(i); Cleare 451:13-24; Thomas 620:7-14.] This split in revenue was based on the collective contributions of the inventors.

28. WashU also agreed to pay WARF \$5,000 for prosecuting the patents in the United States, 33 1/3 percent of certain additional foreign filing-fee estimates, and a 15 percent administration fee, taken from the licensing royalties, for “securing and administering” any license agreements. [JX1 §§ 2.B.(iv), 3.B.]

29. The 1995 IIA further required WARF to “pay to [WashU] its share of Net Revenue due under this Agreement every 12 months by August 31 for the preceding 12-month period beginning July 1 and ending June 30.” [JX1 § 5.B.]

30. The 1995 IIA was not related to Dr. Slatopolsky’s 1993 testing of paricalcitol in rats as described in the 1993 Abbott Development Report. As admitted by Dr. Cleare, Dr. Slatopolsky’s testing did not involve any analysis of phosphorus levels or hyperphosphatemia (the invention claimed in the ’815 patent). [Cleare 310:11-311:18; *see also* Lentz 814:15-816:15, 818:22-819:2.] Dr. Slatopolsky was compensated for that pilot study in a separate Sponsored Research Agreement between him and Abbott. [JX86; Cleare 260:4-261:10, 308:21-309:18; Surber 401:17-402:3; Lentz 803:10-20, 805:1-10, 813:19-814:9; JX322.006.]

His 1993 experiment confirmed what was disclosed in the '925 controlling use patent—that paricalcitol would suppress parathyroid hormone (PTH) levels and have a minimal effect on blood serum calcium levels as compared to the then current standard of care treatment using Calcijex®. [Lentz 807:16-808:13.]

**C. There Was No Intent Between the Parties to Re-evaluate the Relative Value of the '815 Patent Based on Unforeseen Future Events**

31. There is no provision (express or implied) in the 1995 IIA that requires WARF to revisit its assignment of relative value to the '815 patent. [JX1; JX370; Gulbrandsen 696:2-697:14; Cleare 272:12-17; Severson 949:7-10.] Nor was there any evidence that the parties intended for WARF to revisit or re-evaluate the relative value after WARF's initial valuation. [Cleare 272:18-273:11; Severson 948:16-949:6.] Dr. Brandt confirmed that the express terms of the 1995 IIA were clear and that those terms constituted the whole agreement between WashU and WARF. [Brandt 363:1-9, 370:9-371:10, 1046:15-1047:13.]

32. Moreover, as WARF's long-time managing director, Dr. Carl Gulbrandsen, testified, WARF's "standard practice" going back at least 20 years was not to re-evaluate the relative value of any one patent within a larger Vitamin D patent portfolio. [Gulbrandsen 693:1-13.] Re-evaluation of one patent out of a large portfolio of many patents would be "a logistical nightmare" that would necessarily adversely affect the value of each of the other patents in the portfolio and lead to other potential challenges from other stakeholders also based on some unforeseen change in circumstance. [Gulbrandsen 693:14-694:6; Severson 949:11-950:17; *see also* Cleare 319:1-4.]

33. It was not customary practice in the technology transfer industry to re-evaluate. Dr. Cleare admitted that he had never "put reevaluations" into the 50 IIAs that he has handled in his career. [Cleare 318:5-13.] He admitted that he conducted no surveys of other technology

transfer offices or cited any AUTM or industry articles, which discussed re-evaluation. [Cleare 270:20-272:2.] Nor could he identify when and under what specific circumstances would it be customary to revisit the relative value in this case. The one and only example he cited from his eighteen years of personal experience involved one license agreement while at the University of Pennsylvania and a specific milestone agreed to by the parties at the time the contract was executed: re-evaluation *upon FDA approval.* [Cleare 319:6-20.] There was no specific milestone agreed to by WARF and WashU. And it is undisputed that WARF allocated the relative values to the patents in the 1998 WARF-Abbott License *after* Zemplar was approved. [Cleare 199:7-18; Severson 951:16-20.] Therefore, Dr. Cleare's sole re-evaluation example from a license agreement based on an agreed-upon milestone is factually irrelevant to this case. [Severson 951:11-23.]

34. Drs. Gulbrandsen and Severson, each with over 20 years of experience in the technology transfer industry, further testified that they were not aware of any custom to re-evaluate relative values based on some unforeseen future events. [Gulbrandsen 694:7-13; Severson 949:11-950:3.] The issue of re-evaluation has never been raised in AUTM meetings or in discussions with other technology transfer offices. [Gulbrandsen 694:14-695:1; Severson 951:1-10.]

**II. IN ACCORDANCE WITH ITS OBLIGATIONS AS SENIOR PARTY TO THE IIA, WARF SUCCESSFULLY PATENTED THE PARTIES' JOINT TECHNOLOGY AND LICENSED IT TO ABBOTT IN 1998 FOR THE MUTUAL BENEFIT OF BOTH PARTIES**

35. In June 1996, less than a year after WARF and WashU entered into the 1995 IIA, and a full year before the parties' joint technology issued as the '815 patent, WARF reached out to Abbott to license the '815 patent. Abbott was the "logical choice." [Cleare 259:4-14, 263:20-264:8.]

**A. WARF's Long-Standing Relationship with Abbott and Its Prior 1993 License Involving Paricalcitol**

36. Abbott and Dr. DeLuca had a long-standing relationship stemming from the 1970s when Abbott took over the license for Dr. DeLuca's drug calcitriol, which it developed and later marketed under the trade name Calcijex®. [JX279; Gulbrandsen 638:20-642:21.]

37. On January 1, 1993, WARF and Abbott entered into the 1993 WARF-Abbott License related generally to paricalcitol, and a second vitamin D compound that Abbott was also interested in (1 alpha, 25 dihydroxy-19-nor-24, 24-dihomo-cholecalciferol), for use in the field of the "treatment of renal osteodystrophy and suppression of hyperparathyroidism." [JX5.013; UF ¶ 7.]

38. Abbott exclusively licensed all rights to the WARF-owned '497 compound patent and '925 controlling use patent, which covers its primary method of treatment.<sup>3</sup> [JX5; UF ¶¶ 8, 15.] These exclusively licensed patents are listed in Appendix B of the 1993 WARF-Abbott License by their patent application number and referred to as the "Licensed Patents." [JX5.014; Gulbrandsen 647:21-648:18.]

39. The 1993 WARF-Abbott License also granted nonexclusive rights to 28 other related DeLuca patent families, which directly supported paricalcitol and methods of making paricalcitol, various intermediates, and related compounds. [JX5; UF ¶ 9; Gulbrandsen 647:13-

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<sup>3</sup> Both the '497 compound patent and the '925 controlling use patent claim priority to the same March 1989 patent application, U.S. Patent Application No. 07/321,030. [UF ¶¶ 13-14.] During prosecution, the USPTO issued a restriction requirement requesting that WARF split the claims of that application into separate divisional applications. [Gulbrandsen 734:18-735:9; Lentz 786:3-787:5.] As a result, WARF filed separate divisional applications—one application that claimed paricalcitol as a compound (issued as the '497 compound patent on December 24, 1996) and a second application that claimed the use of paricalcitol to treat hyperparathyroidism (issued as the '925 controlling use patent on September 21, 1993). [JX2; JX3; UF ¶ 13; Lentz 786:3-787:5.] The specification of both the '497 compound patent and the '925 controlling use patent is the same. [Lentz 874:10-13.]

20.] These patents were listed in Appendix C and were called “Ancillary Patents.” [JX5.015-23; UF ¶ 9.]

40. The 1993 WARF-Abbott License did not include the ’815 patent, the subject matter of which had not yet been invented. [JX5; UF ¶ 10.]

41. As consideration for the 1993 WARF-Abbott License, Abbott paid WARF a one-time license fee and agreed to pay earned royalties of seven percent of any resulting net sales on a next-generation product based on the exclusively licensed patents (i.e., the ’497 compound patent and the ’925 controlling use patent). [JX5.004; Gulbrandsen 651:23-652:14.] Abbott agreed to pay WARF a five percent royalty on the “Ancillary Patents” or nonexclusively licensed patents. [JX5.004; Gulbrandsen 652:6-23.] Overall, however, Abbott’s *total* royalty obligation to WARF (and its inventors) was capped at seven percent (the royalty rate for the two Licensed Patents). [JX5.004; Gulbrandsen 652:6-23; Mulhern 1109:11-1110:16.]

42. WashU had no involvement in the work that led to the ’497 compound patent or the ’925 controlling use patent, and Dr. Slatopolsky is not an inventor of either patent. [UF ¶ 17; Slatopolsky 120:17-22; Gulbrandsen 645:13-16.]

**B. Abbott Did Not License the Narrower Method-of-Use ’815 Patent Until After the FDA Approved Zemplar**

43. In its June 1996 letter, WARF advised Abbott of the soon-to-issue ’815 patent and requested that it be included as an amendment to the 1993 WARF-Abbott License portfolio, as it would “provide additional protection for Abbott with their new 19-nor product [paricalcitol] on the marketplace.” [JX42.] Before this, Abbott never asked either Dr. DeLuca or Dr. Slatopolsky for a license to the method of use claimed in the ’815 patent application. [Cleare 261:16-262:12, 263:6-15.]

44. WARF also informed Abbott that it “has taken the initiative and entered an agreement” with WashU, and that the addition of the ’815 patent to the Abbott portfolio would result in WashU and Dr. Slatopolsky receiving a portion of the payments that WARF would have otherwise received under the 1993 WARF-Abbott License. [JX42.]

45. WARF received no response from Abbott on the ’815 patent for 21 months. [Cleare 267:7-268:4, 269:21-270:5.]

46. WARF tried again to license the ’815 patent to Abbott. After the patent issued and the FDA approved Zemplar, WARF wrote to Abbott again informing it of the ’815 patent’s issuance and providing a draft amendment adding the ’815 patent to the existing list of Ancillary Patents from the 1993 WARF-Abbott License. [JX47.]

47. The letter states, “[w]e recognize that this technology directly supports the Abbott Zemplar™ product and it is appropriate to add this to the licensed patent list. As an inventor, Dr. Slatopolsky will then be entitled to a portion of the WARF royalties received from Abbott for this product.” [JX47.]

48. Abbott agreed to license the ’815 patent, but the parties did so through a new superseding license agreement, which included almost all of the patents included in the 1993 WARF-Abbott License, plus other patents that had been licensed through amendments since 1993.<sup>4</sup> [UF ¶¶ 30-31; JX376; JX8; Cleare 253:4-18; Gulbrandsen 655:3-24.] This 1998 WARF-

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<sup>4</sup> Abbott had previously amended the 1993 WARF-Abbott License twice in 1996 to expand the licensed field to include “renal osteodystrophy, suppression of the hyperparathyroidism, treatment of psoriasis and the treatment of cancers as specified in the cancer development plan” (Amendment A [JX6]), and also to include “treatment of multiple sclerosis” (Amendment B [JX7]). Neither of these 1996 amendments to the 1993 WARF-Abbott License included the ’815 patent.

Abbott License further expanded the licensed field of use to include all human therapeutics for paricalcitol. [JX8; JX376; Gulbrandsen 653:15-654:21.]

**C. The Material Terms of the 1998 WARF-Abbott License Did Not Differ from the 1993 WARF-Abbott License**

49. Due to Abbott's interest in expanding the franchise and developing other uses for paricalcitol beyond kidney disease, the licensed field of use in the 1998 WARF-Abbott License was expanded from kidney disease to include "all human therapeutics," and the '815 patent, along with six other method-of-treatment patents related to other disease states, was added to the Ancillary Patent group. [JX8.011; JX259; Gulbrandsen 654:6-655:2.] As Dr. Gulbrandsen testified, Abbott and Dr. DeLuca were particularly excited at this time in the possibility that paricalcitol could also be used to treat multiple sclerosis. [Gulbrandsen 655:3-17.] All in all, the 1998 WARF-Abbott License included thirty-one patent families, thirty of which are solely owned by WARF. [JX8.]

50. Other than expanding the licensed field of use [Gulbrandsen 653:15-654:21], the material terms of the 1998 WARF-Abbott License did not differ from the 1993 WARF-Abbott License [Gulbrandsen 652:24-653:14], in which WARF granted Abbott all exclusive rights to the '497 compound patent and the '925 controlling use patent. [JX8; UF ¶ 8.] These exclusively licensed patents were again listed in Appendix B of the 1998 WARF-Abbott License and referred to as the "Licensed Patents." [JX8.012.]

51. The 1998 WARF-Abbott License also granted Abbott nonexclusive rights to the '815 patent and twenty-nine other patent families, which were listed in Appendix C and referred to as the "Ancillary Patents."<sup>5</sup> [JX8.013-26; Gulbrandsen 652:24-653:14.]

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<sup>5</sup> WashU's expert Dr. Cleare testified, based on the wording of the nonexclusive grant clause, that the '815 patent is either exclusively licensed to Abbott or not licensed at all. [Cleare 332:10-

52. Zemplar was already on the market by the time Abbott licensed the '815 patent, and Abbott did not pay WARF anything more for adding the '815 patent to the pre-existing licensed portfolio. [Gulbrandsen 660:4-17; Lentz 821:17-21; Severson 954:18-21; Mulhern 1077:7-15.] Nor did Abbott ask for an exclusive license to the '815 patent upon licensing. [Gulbrandsen 658:21-660:17.]

53. The 1998 WARF-Abbott License had the same royalty structure as the 1993 WARF-Abbott License, including the seven percent royalty cap on Abbott's royalty obligations based on the Licensed Patents (the '497 compound patent and the '925 controlling use patent). [Gulbrandsen 652:24-653:6.]

54. Abbott's payment of royalties from 1998 until March 2015 was solely under the exclusively licensed '497 compound patent and foreign counterparts. [Mulhern 1073:20-1075:4, 1075:12-1076:5.] No royalties were attributable to the Ancillary Patents—including the '815 patent—because the five percent royalty assigned to the Ancillary Patent group was subsumed by the seven percent cap. [Mulhern 1074:17-1075:4.] Abbott ended its royalty obligations under the 1998 WARF-Abbott License in August 2016.<sup>6</sup> [JX491; Mulhern 1083:19-1084:18.]

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334:8.] Dr. Cleare's interpretation is nonsensical in view of the express terms of the 1998 WARF-Abbott License and contrary to the manner in which WARF and Abbott treated the '815 patent under the agreement. [Mulhern 1078:6-1080:14.] Moreover, under this interpretation, Dr. Cleare admitted that all six of the method-of-treatment patents in the Ancillary Patent group also would be exclusively licensed. [Cleare 333:7-22.] Yet, Dr. Cleare opined that these other method-of-treatment patents (other than the '815 patent), despite being exclusively licensed, should be entitled to no value because Abbott never developed paricalcitol to treat those diseases. [Cleare 333:23-334:8.] This position is inherently inconsistent with his specific valuation analysis, which places much greater value on exclusively licensed patents.

<sup>6</sup> In 2012, Abbott assigned its license to the '815 patent to AbbVie Inc. as part of a reorganization of Abbott's worldwide business operations, where it separated into two companies. [JX349.]

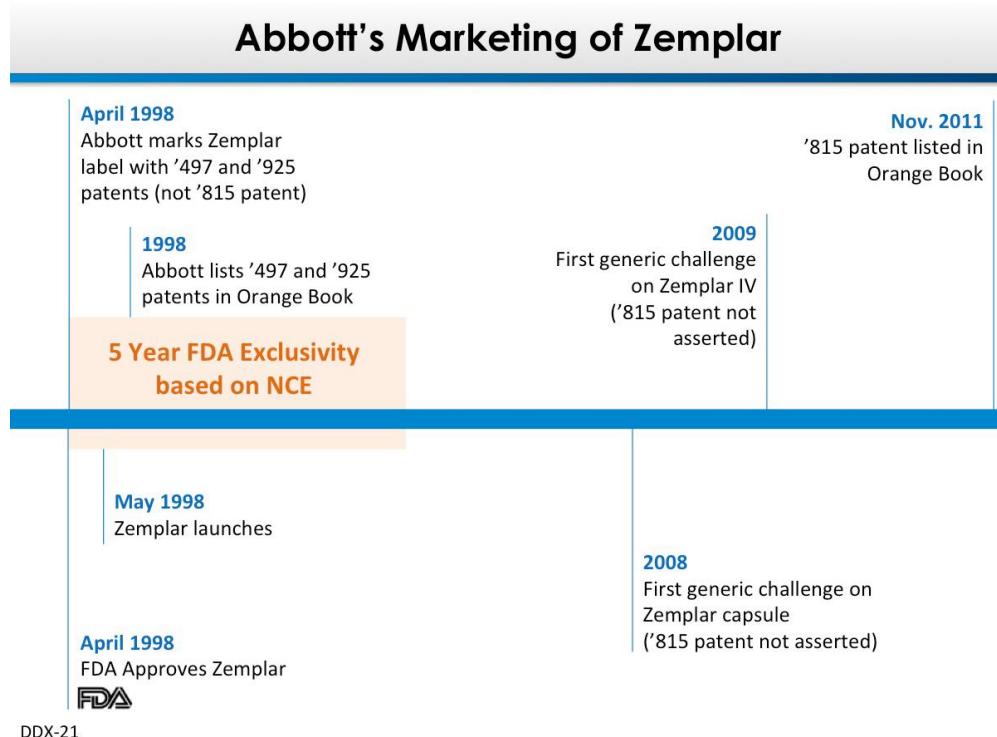
**D. Abbott Did Not Use the '815 Patent Until Late 2011**

55. From Zemplar's approval in May 1998 through November 2011, WARF had no information that Abbott believed that Zemplar practiced the '815 patent, and between WARF and Abbott, Abbott was in a better position to know whether or not Abbott was using the patent.<sup>7</sup> [Cleare 249:3-250:5; Gulbrandsen 664:16-665:7, 665:21-666:3.]

56. As shown in the timeline in Figure 1 and discussed in greater detail below, the FDA had rejected Abbott's request for a renal osteodystrophy indication in 1998, and Abbott did not list the '815 patent in the Orange Book when Zemplar was first approved. [JX262.019; Lentz 823:2-14.] Nor was the '815 patent listed in Zemplar's 1998 label as the dominating '497 compound patent and '925 controlling use patent were. [JX261.004; Gulbrandsen 666:11-22.] The '815 patent also was not asserted in any of the seventeen Hatch-Waxman litigations initiated prior to 2011, including the important first-to-file cases against Teva and Sandoz in 2008 and 2009. [Thomas 607:15-21; Lentz 843:16-844:2.] Abbott did not represent that it was using the patent by virtue of its Orange Book listing until 2011. [Cleare 249:3-7; Surber 483:20-23; Thomas 603:10-12; Gulbrandsen 701:21-702:3; Lentz 822:20-823:1; Mulhern 1099:3-6.]

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<sup>7</sup> The 2008 email from WARF's new Licensing Manager Mark Stoveken ("2008 Stoveken Email" [JX50]) also does not show that WARF knew Abbott was using the '815 patent. The 2008 Stoveken Email was not based on any information from Abbott, but instead represented Mr. Stoveken's personal opinion. As both Dr. Gulbrandsen and Mr. Stoveken testified, the 2008 Stoveken Email was not shared with anyone at Abbott, and nothing ever came from Mr. Stoveken's analysis. [Gulbrandsen 706:15-19, 708:4-16; Stoveken 512:2-7.]

**Figure 1: DDX-21**

### 1. The FDA Rejected the Indication Claimed in the '815 Patent Shortly Before It Approved Zemplar

57. Zemplar only has one FDA-approved indication—"the prevention and treatment of secondary hyperparathyroidism encountered with chronic renal failure." [JX51; Thomas 575:18-22.] It is undisputed that the '925 controlling use patent claims the FDA-approved indication. [UF ¶ 15; Thomas 575:11-17; Lentz 788:11-789:18.]

58. In its New Drug Application submitted on January 17, 1997 [UF ¶ 28], Abbott originally sought FDA approval for two indications: (1) the prevention and treatment of secondary hyperparathyroidism (claimed in the '925 controlling use patent), and (2) the prevention and treatment of renal osteodystrophy (claimed in the '815 patent). [JX262.019.]

59. In April 1998, shortly before Zemplar received final approval, the FDA rejected Abbott's request for an approved indication of renal osteodystrophy. [Lentz 819:20-821:12.] As

explained by the Director, Division of Metabolic and Endocrine Drug Products, in the FDA's review of Abbott's NDA:

The sponsor had initially asked for wording in the indication which included the treatment of osteodystrophy. However, we believe that bone biopsy data are necessary for granting this indication. Although we recognized that a beneficial effect on bone would be the probable outcome of the effective suppression of hyperparathyroidism, we would like a direct histomorphometric demonstration of this.

[JX262.019.]

60. After that, Abbott never pursued approval of an indication for renal osteodystrophy. [Lentz 821:9-12.]

**2. Abbott Did Not Identify the '815 Patent in Zemplar's Label**

61. In Zemplar's 1998 label, Abbott identified both the dominating '497 compound patent and the '925 controlling use patent. [JX261.004; Gulbrandsen 666:11-22.] The '815 patent was not listed. [Gulbrandsen 666:11-18.]

**3. Abbott Did Not List the '815 Patent in the Orange Book upon Approval**

62. Under the Hatch-Waxman statute, innovator pharmaceutical companies are required to list in the Orange Book any patents that claim the drug substance (active ingredient), the drug product (formulation), or an approved method of using the drug, for which "infringement could reasonably be asserted" against an applicant seeking to market a generic version of the drug. [Lentz 823:15-824:3.] The listings in the Orange Book provide notice to generic companies as to which patents cover an approved drug. [Surber 417:17-418:2.] Orange Book listings are publicly available. [Surber 484:24-485:7.]

63. Upon FDA approval, Abbott, as the NDA holder, timely listed the '497 compound patent and the '925 controlling use patent in the Orange Book, and also listed two

Abbott-owned formulation patents (U.S. Patent Nos. 6,361,758 and 6,136,799) once they issued. [JX93A; JX93; Surber 468:11-469:4.]

64. Abbott did not list the '815 patent in the Orange Book upon receiving FDA approval for Zemplar Injection in 1998. [Lentz 822:20-23, 837:17-838:1; Cleare 249:3-15; Thomas 603:3-12.]

65. WARF did not decide which patents to list in the Orange Book. [Gulbrandsen 701:21-702:3.]

66. Even when anticipating generic challenges in 2008, Abbott and WARF signed an amendment to the 1998 WARF-Abbott License to set forth the obligations for generic litigation. [JX9; Gulbrandsen 699:8-701:4.] The patents to be asserted were expressly identified in the amendment. The '815 patent was not listed.

67. It was not until the '925 controlling use patent was about to expire that Abbott made a strategic litigation decision to list the '815 patent in the Orange Book on November 30, 2011. [JX263; Gulbrandsen 701:21-702:3.]

#### **4. The '815 Patent Was Not Asserted in the First-to-File Hatch-Waxman Litigations**

68. As of 2008, Abbott did not contemplate asserting the '815 patent in Hatch-Waxman litigation. The only patents contemplated by Abbott, as evidenced by the 2008 amendment to the 1998 WARF-Abbott License, were the '497 compound patent, the '925 controlling use patent, and the two Abbott-owned patents covering Zemplar's formulation. [JX9; Gulbrandsen 699:8-701:4.]

69. In 2008 and 2009, the '815 patent was also not asserted in first-to-file litigations for Zemplar. [Thomas 607:15-21; Lentz 843:16-844:2.] These litigations were the most

important for protecting the market exclusivity of Zemplar because they set the date for subsequent follow-on generic drug entry. [Lentz 844:12-846:11.]

70. The first suit for Zemplar capsules was filed on November 20, 2008, against Teva. [JX265.] The two patents asserted in the *Teva* litigation were the '497 compound patent and the '925 controlling use patent. [JX265.]

71. The first suit for Zemplar injection was filed on April 1, 2009, against Sandoz. [JX269.] The patents asserted in the *Sandoz* litigation were the '497 compound patent, the '925 controlling use patent, and the two Abbott formulation patents. [JX269.]

72. The '815 patent was first asserted in litigation in February 2012, after the *Teva* and *Sandoz* litigations were settled and the date for first generic entry was established. [JX63; JX67; JX68; Lentz 831:9-13.]

73. As both WashU's experts Dr. Cleare and Mr. Thomas admitted at trial, the '815 patent did not delay entry of any generics, nor did it provide for any longer duration of market exclusivity for Zemplar over the settlements from the litigation of the other Orange Book listed patents and the FDA exclusivity period from the first-to-file cases in which the '815 patent was not asserted. [Cleare 295:12-16, 296:3-12; Thomas 547:16-548:6.]

### **III. WARF ASSIGNED A FAIR RELATIVE VALUE TO THE '815 PATENT IN 1998**

74. The 1995 IIA authorized WARF, and WARF alone, to license the '815 patent as part of a larger portfolio and to assign it a relative value within that portfolio. [JX1; Brandt 363:19-364:4; Cleare 182:16-183:7.]

75. WARF exercised that authority based on its standard licensing and technology transfer practice, and assigned a relative value to all patents within the Abbott portfolio in November 1998. [JX11.]

76. WARF's allocation of relative value to the patents in the 1998 WARF-Abbott License portfolio was consistent with WARF's practices and policies for Dr. DeLuca's Vitamin D portfolios and was fair. As explained in more detail below, WARF properly placed the '815 patent in the Ancillary Patent group (it was not part of the '497 compound patent family) and assigned it the same relative value as every other ancillary patent (most of which had been licensed to Abbott in 1993).

77. WARF's standard practice after licensing was to prepare an Income Division Memo signed by the licensing associate, director of patents and licensing, and managing director, in accordance with its Policy on Allocation of Agreement Income, detailing the manner in which license proceeds (income) are to be distributed among the various licensed patents and their inventors. [JX11; JX10.002.] By policy, WARF distributes 20% of the gross revenue payable under a license to the inventors of all of the patents included in the licensed portfolio. [Gulbrandsen 634:4-635:11; JX10.001.]

78. Each of these income division memoranda adopted a multistep approach: (1) classify licensed patents into two groups ("compound" and "ancillary") based on each patent's status as exclusively ("compound") or nonexclusively ("ancillary") licensed; (2) allocate a share of license income to each group; and (3) assign value to each patent within each group. [Gulbrandsen 647:21-649:1.] Within the "ancillary" groups, WARF always allocated value on a pro-rata or equal basis for each patent family. [Gulbrandsen 658:6-20.]

**A. It Is Fair to Assign a Majority of the Value to the Dominating Compound Patent**

79. WARF's consistent practice for Dr. DeLuca's Vitamin D portfolios was to assign a majority of the value to the compound patent family. [Gulbrandsen 676:8-12, 678:9-23.] It was undisputed at trial that the compound patent family was the most important and valuable

patent because it dominates all other patents and uses for the drug. [Cleare 205:1-6; Gulbrandsen 650:8-20, 676:21-677:6; Thomas 595:10-22, 613:24-614:8; Lentz 826:21-827:3; Brandt 359:20-360:3; DeLuca 767:5-24.] As WARF's witnesses Mr. Lentz and Dr. Gulbrandsen testified, obtaining exclusive rights to the compound patent was essential for a pharmaceutical company like Abbott, which was going to invest hundreds of millions of dollars to develop the drug. [Gulbrandsen 676:21-678:2; Lentz 790:21-792:12.] It is undisputed that the '815 patent cannot be practiced without having rights to the '497 compound patent. [Thomas 580:9-16.]

80. The evidence also established that WARF's practice to assign a majority of value to the compound patent was consistent with WARF's policy that WARF "may assign a percentage to each Licensed Patent to reflect the disproportionate value of Patent Families in the development and commercialization of product(s) under the agreement." [JX10.003.] As Dr. Gulbrandsen explained, "it's the compound patent family . . . the licensee really needs to do their development and commercialization." [Gulbrandsen 689:8-690:15; *see also* Cleare 207:3-208:2.]

**B. WARF's Blended Approach in Assigning Relative Value to the Ancillary Patents Is Meant to Be Fair in a Dynamic Marketplace**

81. Aside from its practice of classifying its patents into compound and ancillary patent groups, WARF did not as a matter of practice make patent-specific valuations or conduct any infringement analyses for its ancillary patents. [Gulbrandsen 651:6-22, 663:11-664:6; JX39.] Dr. Cleare admitted that even today, he lacked knowledge regarding how Abbott manufactured Zemplar and how Abbott valued any of the Ancillary Patents. [Cleare 231:22-233:13, 286:1-287:6, 289:12-18; *cf.* Lentz 827:4-829:5; Gulbrandsen 651:6-22, 690:21-691:15.]

82. By assigning equal value to the Ancillary Patents, WARF's "blended" approach recognizes that the value of a patent may change over the patent's life based on how WARF's licensees decide to use a licensed patent in future years. As Dr. Gulbrandsen explained:

So the blended approach meant that if you were early on in being included in the license agreement, had an earlier filing date, and you expired during the term of the license, you would still receive payments until the termination of the license because it was felt at the early stage you provided support, but the greatest amount of royalty came in at the later stage, so you should share equally with everybody and that was the philosophy of the blended approach.

[Gulbrandsen 672:10-673:10.] With this blended approach to royalty allocation, WARF does not as a matter of policy and practice, take out early or expired patents from the portfolio after licensing, and similarly does not penalize later-invented patents (like the '815 patent) that were later added to the licensed portfolio. [Gulbrandsen 673:7-10.]

83. It was not necessary for WARF to conduct an infringement analysis to determine that Abbott practiced the '497 compound patent. [Gulbrandsen 663:21-664:6, 725:22-726:6.] The '497 compound patent covered any and all uses of the drug. [Cleare 288:20-299:7.]

84. WARF's statements in 1995 and 2001 to WashU that it didn't know how its licensee would use a given patent in the future were not misleading, but were truthful. [Gulbrandsen 670:13-671:7, 691:16-692:16; Severson 971:12-15.] As Mr. Lentz testified, pharmaceutical companies "value their confidential information" and limit the information shared with universities regarding how the company will use the licensed technology. [Lentz 780:9-781:15.] There is no evidence that WARF knew how Abbott was or was not using the Ancillary Patents. Certainly, Abbott was not using the '815 patent to protect against generic exclusivity from 1998 until 2011.

**C. WARF's Assignment of Relative Value to the 1998 WARF-Abbott License Was Consistent with Its Policies and Practices and Was Fair**

85. For the 1998 WARF-Abbott License, WARF assigned the core compound patent family a relative value of 70%.<sup>8</sup> [Gulbrandsen 674:17-675:18; Severson 990:21-991:23.] Each of the thirty-one ancillary patent families was then assigned an *equal* share of the remaining 30% (i.e., 0.97% each). [JX11; Gulbrandsen 674:9-675:18.] As an “Ancillary Patent,” the ’815 patent was allocated a 0.97% (30/31) share of the licensed proceeds. [JX11; JX49.]

86. For the 1998 WARF-Abbott License, twenty-seven inventors, including WashU’s Dr. Slatopolsky at WashU, received royalties. [JX11; Gulbrandsen 695:12-696:1.]

87. The 70/30 split between the compound patent families and the ancillary patent families for the 1998 WARF-Abbott License was consistent with Dr. DeLuca’s other vitamin D licenses, which had splits of 80/20 and 60/40 between core and ancillary patents. [Cleare 215:4-9; Gulbrandsen 678:9-679:4; Thomas 597:6-19; JX16.0031; JX18.034; JX19.027; JX20.011.]

88. In the Multiple Sclerosis Amendment B to the 1993 WARF-Abbott License (which was executed in 1996 and applied only to uses in the multiple sclerosis field), Abbott and WARF agreed to broaden the field of use to specifically include the treatment of multiple sclerosis. [JX7; Gulbrandsen 656:1-12.] The Income Division Memo for that amendment, which allocated a 29% relative value to WARF’s multiple sclerosis patent, applied only to uses in the multiple sclerosis field in view of Abbott’s agreement to pay separate royalties of 2%, 3%, or 5% on that patent. [JX7; JX15.] Under the terms of the superseding 1998 WARF-Abbott License, Abbott no longer agreed to pay separate royalties on the “Multiple Sclerosis Patent.” [Gulbrandsen 656:1-21.] Accordingly, that patent was given a relative value within the portfolio

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<sup>8</sup> The compound patent family, identified as “P89130US” in the Income Division Memo, included both the ’497 compound patent and the ’925 controlling use patent. [JX11; Gulbrandsen 675:10-676:7.]

*equal* to the '815 patent and the rest of the Ancillary Patents after the 1998 WARF-Abbott License was executed. [Gulbrandsen 656:16-19, 658:6-12, 740:8-15.]

**IV. WARF ACTED AS A RESPONSIBLE SENIOR PARTNER BY REGULARLY CORRESPONDING WITH WASHU AND ANSWERING ALL OF ITS QUESTIONS**

**A. WARF Kept WashU Updated Regarding Prosecution and Licensing Efforts**

89. Since the establishment of the 1995 IIA, WARF has communicated regularly with WashU, keeping them apprised of developments relating to the prosecution, maintenance, and licensing of the '815 patent. [Cleare 179:8-19 ("[C]ooperation includes communication and I would think they would work together in the prosecution, maintenance, and licensing of the final patent.").]

90. From the outset, WARF treated WashU fairly and kept them apprised. It started on July 21, 1995, when Mr. Bremer included a copy of the '815 patent application in his initial letter to Dr. Brandt.<sup>9</sup> [JX39.]

91. On September 1996, WARF consulted with WashU regarding its intent to file foreign applications. [JX172.]

92. On January 21, 1997, WARF wrote WashU about its foreign filing intentions and provided a foreign patent cost estimate to see if WashU would be interested in patent protection outside the United States. [JX43.]

93. On September 19, 1997, WARF informed WashU that the '815 patent had issued in the United States and enclosed a copy of the issued patent and updated foreign filing prosecution and licensing activity. [JX44.] In that letter, the WARF licensing associate stated,

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<sup>9</sup> As Dr. Brandt testified, she expected that WARF would contact Dr. Slatopolsky directly regarding patenting issues. [Brandt 1042:2-21.]

“I am actively pursuing several leads in licensing this technology and will provide you periodic updates on my progress.” [JX44.]

94. On May 13, 1998, WARF informed WashU via facsimile that it was “working on incorporating the DeLuca/Slatopolsky technology . . . as an amendment to an existing license agreement.” [JX45.]

95. On October 26, 1998, WARF informed WashU that the ’815 patent had been successfully added to the “Abbott License Agreement this summer,” and that “Abbott Laboratories received approval of Zemplar® in April 1998 and they subsequently launched this product in late May 1998.” [JX48.]

96. Every one of these correspondence ended by stating that if WashU had any questions or concerns to please contact WARF. [JX39; JX43; JX44; JX45; JX48.] Every time WashU asked a question from 1995 through this dispute, WARF promptly responded to WashU. [Kratochvil 391:6-11; Severson 971:15-19.]

**B. WARF Began Paying WashU Its Share of Royalties After Zemplar® Was Approved in 1998**

97. On November 25, 1998, WARF provided WashU with its first royalty report and payment, explaining that the disbursement is “based on the first royalty revenue received from Abbott Laboratories for their product Zemplar®.” [JX21.]

98. The letter also included an explanation of the calculation of the distributed amount that began with the amount of royalty income allocated to the ’815 patent and then deducted the agreed-to fifteen percent administration fee to determine the adjusted royalty income. [JX21.] Dividing this amount by one-third yielded WashU’s share of the royalties for the ’815 patent—half of which was applied to cover patenting costs per the 1995 IIA and half of which was disbursed as a check to WashU. These calculations were shown in the letter, which

ended with an invitation to WashU to contact WARF if they “ha[d] any questions or comments.” [JX21.]

99. As WashU admits, the details included in this royalty report allowed for the simple calculation of the total sales of Zemplar to Abbott, as well as the seven percent capped royalty to WARF. [Surber Dep. Tr. 192-193.]

100. After this first royalty report and payment, WARF sent a royalty report along with a check annually to WashU, with letters sent in 1999, 2001 (twice), 2003 (twice), 2004, 2005, 2006, 2007, 2008, 2009, 2010, 2011, 2012, 2013, 2014, 2015, 2016, and 2017. [JX22-38; JX484-486.]

101. Each year, WARF paid WashU its share of royalties based on the same relative value that WARF assigned in 1998. [Mulhern 1086:2-5.] WARF never missed a payment or underpaid WashU. [Gulbrandsen 709:4-14; Mulhern 1086:2-17.]

102. Each of WARF’s royalty payments to WashU was accompanied by a letter setting forth WARF’s royalty calculations, including the total amount of royalties received by WARF attributable to the ’815 patent, the administration fee, the adjusted royalty income, the shared royalty, the patent expense costs, and the total due to WashU. [JX22-38; JX484-486.]

103. In every instance, the letters closed with an invitation for WashU to contact WARF if they had any questions concerning the report or payment. [JX22-38; JX484-486.]

**C. WashU Accepted and Cashed Zemplar’s Royalty Checks Even After Disputing WARF’s Allocation of Relative Value**

104. WashU accepted and deposited each of the royalty checks from 1998 to 2012 without any comments or questions. [Gulbrandsen 709:15-23; Mulhern 1086:2-17.] Even after raising a dispute in 2012 over WARF’s assignment of relative value, WashU continued to accept and deposit the annual checks WARF sent in 2013 to 2017. [Mulhern 1086:10-17.] Like the

1998-2012 checks, each of the 2013-2017 checks was calculated using the 0.968% relative value. [Mulhern 1086:2-5.]

**D. WashU Did Not Maintain Adequate Files or Control over the 1995 IIA**

105. It was revealed during discovery that WashU's Office of Technology Management was not actually aware of Dr. Slatopolsky's research activities. [Brandt 346:3-18; Surber 438:8-19.] Nor did WashU maintain active files on the 1995 IIA or take an active role in reviewing the correspondence WARF sent it. [Brandt 369:20-370:8; Kratochvil 382:1-9, 384:7-22.] In 2010, WashU wrote to WARF asking for information regarding the licensing of the '815 patent because WashU's technology transfer office "has no records regarding patent and licensing activity" under the 1995 IIA. [JX181.002 (DDX38); Kratochvil 385:23-387:3; Surber 441:13-20; Kratochvil Dep. Tr. 115:21-117:15.] Indeed, as discovery showed, the only letters WashU had in its files was the 2001 Letter and the letters accompanying the royalty checks. [Surber 415:12-21, 442:21-443:7.] WashU did not have any of the 1995 Bremer/Brandt letters or any of the other letters WARF sent apprising it of WARF's prosecution and licensing activities. [Surber 441:13-20.]

106. In addition, WashU's witnesses testified that they made no independent effort to monitor the '815 patent, the IIA, or Abbott's marketing of Zemplar. [Kratochvil 376:20-377:7, 381:20-382:9, 1050:10-17.]

107. As Dr. Brandt admitted, WashU did not typically review issued patents; they simply filed them in a file cabinet. [Brandt 1048:16-1049:9.] And no one at WashU reviewed

the '815 patent until 2007.<sup>10</sup> [JX186 (DDX45); Kratochvil 1052:17-1054:9; Surber 442:21-443:7, 446:4-9.]

108. Jon Kratochvil was the business development manager assigned to the 1995 IIA starting in 2000 through at least 2012. [Kratochvil 376:11-19.] He testified that he didn't have a copy of the IIA and the '815 patent until 2007. [JX186 (DDX45); Kratochvil 1051:3-1053:18.] He admitted that he did not have any concerns about the IIA up to the time when he was made aware of the present dispute. [Kratochvil 391:22-392:12, 377:2-11, 379:7-24.]

109. While aware of the Orange Book, Mr. Kratochvil never monitored patent listings in the Orange Book, even when WashU was the senior party to an inter-institutional agreement. [Kratochvil 1049:15-1051:2.] Nor did Mr. Kratochvil make any effort to monitor whether the '815 patent covered Zemplar. [Kratochvil 1050:14-17.]

## V. WASHU UNREASONABLY DELAYED IN FILING THIS SUIT

### A. WashU Stayed Silent for More Than a Decade After Knowing the '815 Patent's Relative Value in 2001

110. In April 2001, in response to an inquiry from WashU, WARF sent a detailed letter to WashU, explaining how it assigned the relative values to the licensed patents based on its blended payout policy. [JX49.] WARF explained that the compound patents, which were identifiable as at least the '497 compound patent (and the '925 controlling use patent) through review of the Orange Book, was allocated 70 percent of the total royalty income, and that the thirty-one later-invented or "Ancillary Patents," which included the joint '815 patent, were allocated an equal share of the remaining 30 percent of the total royalty income. [JX49.] Similar

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<sup>10</sup> While WashU's internal documents showed that WashU noticed that it was not listed as an assignee on the '815 patent in 2007, [JX186 (DDX45)], it said nothing to WARF until after 2012 when it received the Hospira subpoena, [Surber 454:1-21].

to the explanation provided by Mr. Bremer during negotiation of the 1995 IIA [JX39], WARF again explained its “blended payment” policy to WashU:

It is WARF’s policy to allocate evenly among these patents regardless of whether or not the patent is actually currently being used by the Licensee. This is because, in many cases, it is difficult if not impossible for WARF to determine whether or not the patent is being used by the Licensee at this time. However, WARF believes that the patent adds some value to the entire portfolio and that, since the license runs to the last of the patents to expire there should be some blending over the lifetime of the License so that all patents in the License benefit from having been licensed.

[JX49.] WARF further explained that WashU receives one-third of 0.97% of the total royalties generated after deducting WARF’s 15% administration fee. WARF also told WashU that, while it considered the amount of total royalties paid by Abbott to be Abbott’s proprietary and confidential information, WashU could “reverse the calculation provided to arrive at th[e] royalty amount paid to WARF.” [JX49.] WARF wrote that WashU should contact WARF if it had any further questions. [JX49.]

111. Over the next eleven years, WashU never raised a single concern, comment, or question, either internally at WashU or of WARF, about the relative value WARF assigned to the ’815 patent in 1998. [Gulbrandsen 692:17-24; Surber 463:12-464:2; Kratochvil 376:20-377:7, 381:20-382:9, 383:22-385:6; Severson 970:5-9.] WashU did not review any publicly available information concerning Zemplar®, its Orange Book listings, or Dr. DeLuca’s patents. [Kratochvil 1050:10-21; Cleare 283:11-285:24; Severson 970:14-23.] WashU did not seek any information from Dr. Slatopolsky, even though he had separately entered into a sponsored research agreement with Abbott and was conducting biological testing on paricalcitol as early as 1993. [Brandt 346:3-18; Surber 438:8-19, 452:16-453:20.] From 2001-2012, WashU took no action at all to evaluate the assigned relative value. [Kratochvil 376:20-377:7, 381:20-382:9.] WashU only received and deposited its royalty checks from WARF. Mr. Surber, WashU’s

corporate representative, even admitted that there was “no reason” for WashU to do anything more related to WARF’s valuation of the ’815 patent from 2001 to 2012. [Surber 463:12-16.]

112. If there is any blame for WashU’s lack of knowledge regarding the ’815 patent and the 1995 IIA, the blame lies with WashU for not asking any questions from 2001 until 2012. [Severson 973:4-974:8.]

**B. WashU Filed the Lawsuit Based on Abbott’s Listing of the ’815 Patent in the Orange Book and the Same Information It Had in 2001**

113. WashU first expressed concern about WARF’s 1998 assignment of relative value in 2012. [Surber 463:20-464:2; Severson 970:5-13.] In this initial prelitigation correspondence, WashU’s claims were based on allegations of a total breach of contract. [JX195 (“Over ten years ago, purportedly acting under the ‘authority’ accorded it under the [1995 IIA], WARF assigned a ‘relative value’ to the ’815 patent of 0.968% of WARF’s license revenues for the bundle of Vitamin D patents exclusively licensed to Abbott.”).]

114. WashU requested that WARF provide (1) the relative values assigned to the ’497 compound patent and the ’925 controlling use patent, (2) whether the relative values assigned to the patents had changed since WARF’s 2001 Letter, (3) WARF’s share of the total royalties generated, (4) the identity of the thirty WARF-owned Ancillary Patents in the 1998 WARF-Abbott License, and (5) whether any settlements in the litigations resulted in the generation of royalties. [JX195; JX196; JX198.]

115. In response, WARF noted that none of the settlements had generated any royalties, and explained that its payments were fair and within the discretion that the parties’ 1995 IIA specifically granted to WARF. [JX197.] WARF explained:

WARF’s ’497 compound patent (and its family) has been the primary driver in preserving market exclusivity against Paragraph IV generic challenges. It is the compound patent that is the gatekeeper patent; without a license to it, the other patents directed

to methods of using paricalcitol are meaningless and largely irrelevant.

[JX197.] WARF proposed holding further discussions after the litigations challenging the infringement and validity of the '815 patent were resolved. [JX197.] To that end, WARF proposed continuing the parties' standstill agreement, originally entered into on April 9, 2013, until February 1, 2014. [JX199; JX202.]

116. WashU filed suit on December 26, 2013, alleging claims for breach of contract, and breach of the implied covenant of good faith and fair dealing.<sup>11</sup> [JX337.002.] Both in its complaint and at trial, WashU admitted that it filed suit in 2013 based on the same information about WARF's valuation of the '815 patent that it had in 2001. [Surber 433:9-15; JX337.012-013.] The only change in circumstance was Abbott's late listing of the '815 patent in the Orange Book and that patent's assertion in litigation, which was unforeseeable and not within WARF's control. [Surber 433:9-15.]

### C. WashU's Claims Are Barred by the Statute of Limitations

117. The 1995 IIA requires WARF to assign a relative value to the '815 patent, once, upon licensing. [JX1 § 3.A.(iii).]

118. WARF assigned a relative value on November 10, 1998. [JX11.]

119. The evidence established that by 2001 WashU knew:

- The unambiguous terms of the IIA;
- The '815 patent was successfully patented and licensed to Abbott;
- The licensed drug was Zemplar;
- The compound patent family gets 70% of the relative value;

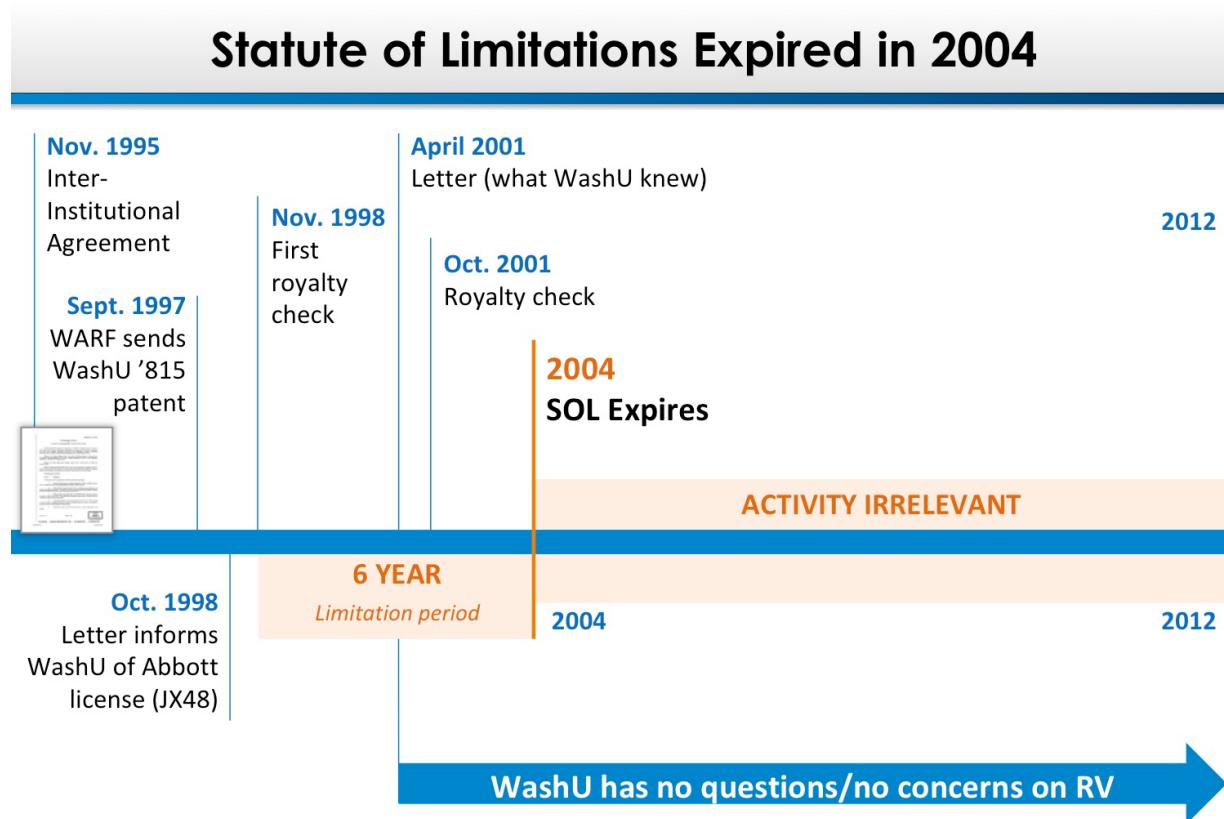
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<sup>11</sup> WashU also alleged claims for breach of fiduciary duty and equitable accounting. [JX337.002.] Those claims are no longer pending. See D.I. 154 at 1-2.

- The remaining 30% of the relative value went to the 31 Ancillary Patents shared equally (.968%);
- WashU receives 1/3 of the .968% relative value(1995 IIA);
- The calculation to determine WARF's royalties;
- The approved indications in Zemplar's label (public);
- The '815 patent was not listed in the Orange Book (public);
- The '497 compound patent and the '925 controlling use patent were listed in the Orange Book (public); and
- The DeLuca patents on 19-nor Vitamin D Compounds (public).

[JX49; Cleare 281:15-285:24; Surber 466:15-20, 483:20-484:11.]

120. As shown in the Figure 2, WashU did not file suit within the six-year statute-of-limitations period. [JX337.]



DDX-403

**Figure 2: DDX-403**

**1. The Annual-Payment Exception Does Not Apply Because There Was No Intent or Duty to Re-evaluate**

121. There is no provision (express or implied) in the 1995 IIA that requires WARF to revisit its assignment of relative value to the '815 patent. Nor did the parties intend for the relative value to be re-evaluated based on some unspecified occurrence that might happen in the future.

122. WashU mischaracterizes the testimony of Dr. Severson when it alleges that "WARF's own expert agrees that WARF had a duty to revalue the patent if it learned of evidence showing that its original valuation was improper." [D.I. 145, Ex. 11 (WashU's Proposed FOF) ¶ 107.] Dr. Severson was asked about a hypothetical situation that has no place

in this case: would WARF have a duty to re-evaluate if WARF learned that it had made a mistake in its original valuation. There was no “mistake.”

123. There is no evidence that WARF made a “mistake” in assigning the ’815 patent a relative value equal to that of the other Ancillary Patents based on its standard practices and policies. Based on Abbott’s listing of the ’815 patent in the Orange Book in 2011 and the patent’s assertion in follow-on Hatch-Waxman litigations in 2012, WARF could not somehow know back in 1998 that the ’815 patent was any more important than any of the other 30 WARF-owned patents in the Ancillary Patent group.

124. While circumstances changed when Abbott listed the ’815 patent in the Orange Book, WARF’s blended approach accounted for such changes in a licensee’s actions.

## **2. Equitable Estoppel as a Defense to the Statute of Limitations Does Not Apply**

125. WashU failed to meet its burden to establish that WARF should be equitably estopped from asserting its statute-of-limitations defense.

### **a. WashU Presented No Evidence of Detrimental Reliance on Any WARF Action in Failing to File Suit**

126. WashU presented no evidence of the reaction its Office of Technology Management had, if any, after receiving WARF’s 2001 Letter. Indeed, none of WashU’s witnesses (Brandt, Kratochvil, or Surber) had knowledge of the 2001 Letter in the relevant time frame. [Brandt Dep. Tr. 30:8-11; Kratochvil Dep. Tr. 100:21-105:10; Surber 438:20-439:12.]

127. Both Dr. Slatopolsky and Jon Kratochvil, WashU’s Business Manager during the 2000s, were aware of the amount of money WashU was receiving by 2001 and were pleased with the amount received prior to becoming aware of this litigation. [Slatopolsky 133:9-134:5, 135:2-136:7; JX185 (DDX72); Kratochvil 392:6-12, 384:22-385:6, 1054:10-15; JX186 (DDX45).] Regarding the sufficiency of the amounts WARF paid WashU, Mr. Kratochvil

testified, “[i]f something looked off, then it’s quite possible I would have followed up. Nothing looks off from this point of view.” [Kratochvil 384:7-16.]

**b. WARF Did Not Fraudulently Conceal Any Information from WashU**

128. WARF did not fraudulently conceal information or act inequitably toward WashU.

129. **1998 Email [JX46]:** WARF did not conceal any license agreement involving the '815 patent. At the time of WashU's request, May 13, 1998, the 1998 WARF-Abbott License did not exist, and there was no license to the '815 patent to give WashU. [See JX8 (effective July 8, 1998).]

130. While the 1998 WARF-Abbott License ultimately did not contain an express confidentiality provision, Dr. Gulbrandsen testified that WARF “prides itself on protecting confidentiality.” [Gulbrandsen 704:18-705:12.] It does not share license agreements outside of WARF, including with inventors, faculty, or administration—consistent with Ms. Kirkpatrick's 1998 statement: “As per confidentiality provisions, I am not at liberty to provide you copies of our license agreements with any other parties. *I would think that your office would have the same restrictions.*” [JX46; Gulbrandsen 704:18-705:20.] Dr. DeLuca confirmed WARF's practice, stating that he has never seen one of his license agreements. [DeLuca 765:22-766:10.]

131. WashU never asked WARF to seek permission from Abbott for WashU to see the license. Nor did it ever raise the issue again. Since WashU never raised the issue again, WARF had no reason to take any further action.

132. WashU had no copy of the 1998 email in its files, and there is no evidence that anyone at WashU in subsequent years (including from 2001 through 2004) actually had knowledge of that 1998 email.

133. **1998 “Directly Supports” Letter [JX47]:** As WashU’s expert Dr. Cleare concedes, the 1998 letter was an attempt by WARF to license the ’815 patent for both WARF’s and WashU’s mutual benefit in accordance with the terms of the 1995 IIA. [Cleare 263:23-264:8, 269:21-270:5.] WashU presented no testimony from the author of the letter, Ms. Kirkpatrick, who was the WARF licensing associate at that time. Nor did WashU present testimony from Ms. Mershimer of Abbott, who received the letter. Therefore, there is no evidence of the intent or meaning behind Ms. Kirkpatrick’s statement that the ’815 patent “directly support[ed]” paricalcitol. [See Gulbrandsen 663:11-16 (“I don’t know what she meant.”).]

134. **Recordation Coversheet Error [JX56]:** The ’815 patent did not list WashU as a co-owner due to an unintentional error made by WARF’s outside counsel in the assignment cover sheet that accompanied the signed assignment identifying WashU as Dr. Slatopolsky’s assignee. [JX56; Severson 962:2-963:2.] Neither WashU nor WARF recognized the mistake when WashU was not listed as an assignee on the face of the ’815 patent. [Cleare 313:6-314:10; Severson 962:18-22.] When this error was finally brought to WARF’s attention in 2012, WARF promptly corrected this mistake. [JX55; JX419; Cleare 315:15-18; Severson 963:3-10.]

135. **WARF’s 2001 Letter [JX49]:** WashU failed to present evidence that the 2001 Letter was misleading, when it was written in 2001. WashU failed to present a witness with personal knowledge of the 2001 Letter. [Kratochvil Dep. Tr. 100:21-105:10; Brandt Dep. Tr. 30:8-11; Surber 438:20-439:12.] The opinions of Mr. Surber, a lawyer for WashU from present day who was not even aware of the IIA, the ’815 patent, or the April 2001 letter until 2012, are unreliable evidence. [Surber 938:20-939:12.] Dr. Cleare admitted that he reviewed the 2001 Letter in hindsight “as if [he] was a WashU person.” [Cleare 208:21-209:11, 296:13-297:10.]

136. First, WashU argues that WARF's statement in the 2001 Letter that "[t]he compound patents are allocated seventy percent (70%) of the total royalty income in accordance with WARF's regular practice in licensing and allocating royalties in a suite of patents for its Vitamin D portfolio" is misleading because it falsely represents WARF's policy. There is nothing false or misleading, however, about WARF's statement. It is undisputed that the '925 controlling use patent and the '497 compound patent are members of the same patent family, that WARF kept patent families together when assigning a relative value, and that the '497 compound patent family was assigned seventy percent of the total royalty income, consistent with the 80/20 and 60/40 splits that are found in WARF's other vitamin D portfolios. [Gulbrandsen 674:17-675:18, 676:8-18, 678:9-23; Severson 990:21-991:23.]

137. Second, WashU argues that WARF made a misleading affirmative assertion when it stated in the 2001 Letter that "it is difficult if not impossible for WARF to determine whether or not the patent is being used by the Licensee at this time." It is undisputed that WARF had a very specific practice in place when it assigned relative values to all licensed patents within the 1998 Abbott portfolio—one that employed a blended payout. [Gulbrandsen 672:10-673:10.] WARF informed WashU of this policy first during negotiation of the 1995 IIA, and again in the 2001 Letter. [JX39; JX49.] WARF did not, as a matter of its practice, make patent-specific valuation decisions or conduct any infringement analyses for the Abbott-licensed patents.

138. **Orange Book Listing and Notice of Litigation:** WashU alleges that WARF failed to communicate Abbott's listing of the '815 patent in the Orange Book and assertion of the patent in follow-on Hatch-Waxman litigations concerning Zemplar. Neither of these events is relevant to WashU's equitable-estoppel allegations because they occurred outside the limitations period. COL ¶ 43. In addition, the parties expressly contemplated in the 1995 IIA that the '815

patent could be asserted in litigation against a generic challenger and explicitly negotiated for that possibility. [JX1 § 9.] WARF was not required to provide notice of the suits to WashU or to discuss its decision to file suit with WashU. [Gulbrandsen 702:12-703:2.] Likewise, the 1995 IIA did not require WARF to monitor the publicly available Orange Book listings or provide such information to WashU. Indeed, as WashU's Jon Kratochvil admitted, when WashU is the senior party, it never monitors Orange Book listings. [Kratochvil 1050:22-1051:2.] There is no evidence that WashU's lack of immediate knowledge about the listing, which was done by Abbott and not WARF, adversely affected it.

**D. WashU's Claims Are Barred by Laches**

139. WashU's delay in filing suit was unreasonable and inexcusable.

140. Despite having sufficient knowledge in 2001 about WARF's relative valuation of the '815 patent, WashU did not object or otherwise contest WARF's valuation until 2012. [Gulbrandsen 692:17-24; Surber 463:12-464:2; Kratochvil 376:20-377:7, 381:20-382:9, 383:22-385:6.]

141. From 2001 until 2012, WARF lacked any knowledge that WashU would assert a breach-of-contract case because WashU accepted and cashed every royalty check without question. [Gulbrandsen 709:15-23; Mulhern 1086:2-17.]

142. Because of WashU's lack of diligence, WARF has paid 20 percent of the licensing revenue it received from Abbott to 26 other inventors, in addition to WashU, based on the same relative valuation established in 1998 for the Abbott portfolio. [Gulbrandsen 634:4-635:11, 695:12-696:1; JX10.001; JX11.]

143. Had WashU raised its objections prior to 2012, WARF would have had notice of a possible challenge to its blended valuation. WARF could have withheld payment of the royalties that WashU contends should be allocated to the '815 patent until WashU's valuation

challenge was resolved, or even re-appropriated the assigned relative value if necessary after resolution of the dispute, instead of making payments over the past 14 years.

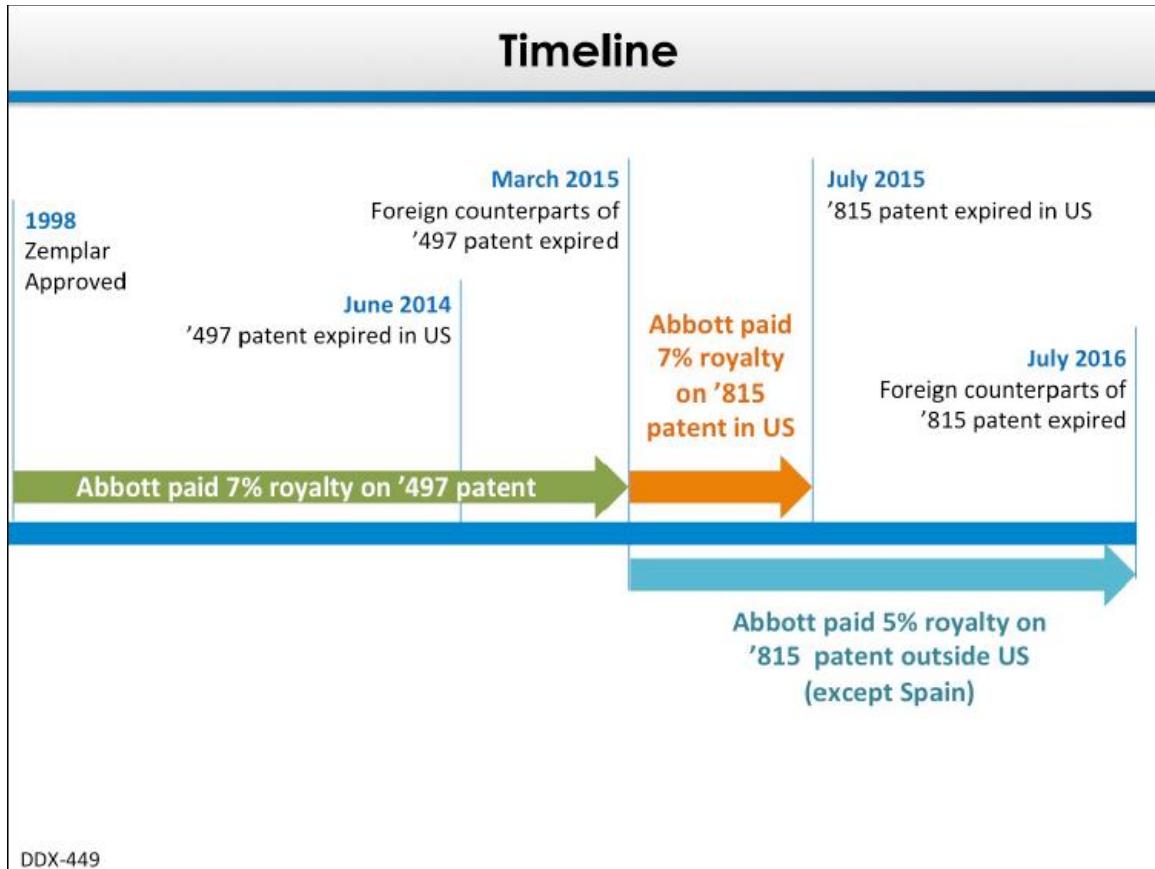
144. Indeed, this approach was discussed specifically with WashU when it raised concerns in early 2013. [JX197 (counsel for WARF stating, “It is certainly true that the ’815 patent expires later than the ’497 patent, but as you know, Hospira is currently challenging both infringement and validity, and if it is successful, then the ’815 patent will not convey any extra value. Thus, we reiterate that it is premature to get into this debate now. In the event that the ’815 patent survives longer than the ’497 patent, then we agree that further discussions would be appropriate at that time, and will commit to engaging in such discussions promptly and sincerely.”).]

145. WARF has suffered economic prejudice as a result of WashU’s unreasonable delay.

**VI. WARF PAID WASHU ROYALTIES FOR 16 YEARS EVEN THOUGH THE NARROWER METHOD-OF-USE ’815 PATENT WAS DOMINATED BY THE ’497 COMPOUND PATENT DURING THAT TIME FRAME**

146. WashU’s damages are based on hindsight and assume that WARF would have known in 1998 about certain facts and circumstances of the ’815 patent that didn’t happen until 2011 and 2012. [Cleare 296:23-297:10.]

147. WARF’s financial analysis shows that the ’815 patent contributed only \$4.1 million in additional royalties at the end of the life of the portfolio. Before March 2015, the ’815 patent generated nothing in additional royalties because of the seven percent cap on Abbott’s royalty payments and the dominance of the ’497 compound patent, as WARF’s expert Carla Mulhern testified. [Mulhern 1076:14-1077:6.] As shown in Figure 3 below, after March 2015, Abbott paid a 7% royalty on the ’815 patent in the United States and Spain and 5% in other countries. By then, Zemplar sales had diminished because of generic competition.

**Figure 3: DDX-449**

148. The '815 patent did not delay entry of any generics and therefore failed to provide any longer exclusivity for Zemplar, even with its listing in the Orange Book and assertion in litigation. [Lentz 846:3-11; Cleare 295:12-16, 296:3-12; Thomas 547:23-548:6; Mulhern 1093:15-22.]

149. The amount of royalties WashU actually received over a period of 18 years was about the same as its share of incremental income from the '815 patent. [Mulhern 1097:5-16.] The present value of actual payments to WashU was about \$1.5 million. [Mulhern 1096:6-13.] WashU's share of \$4.1 million in incremental income from the '815 patent was only \$1.2 million. [Mulhern 1090:24-1092:16.] This comparison validates WARF's blended approach. [Mulhern 1096:14-1097:16.]

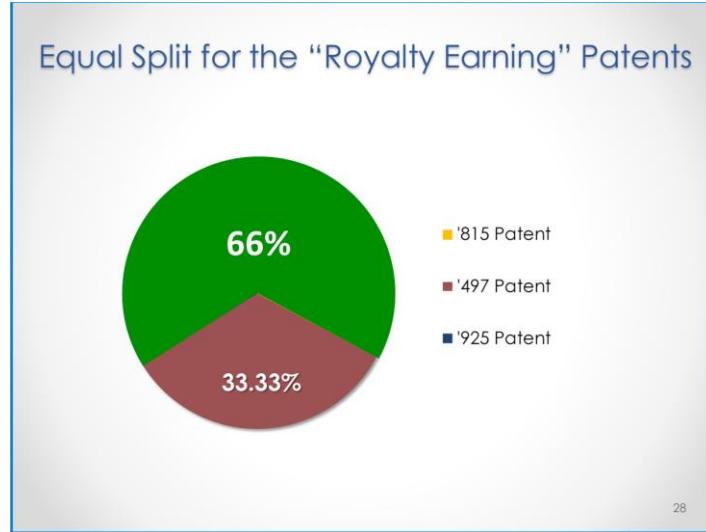
150. There was no actual financial injury to WashU. [Mulhern 1097:17-19.]

**A. WashU’s Expert’s Damages Theory Is Uncertain and Should Be Rejected**

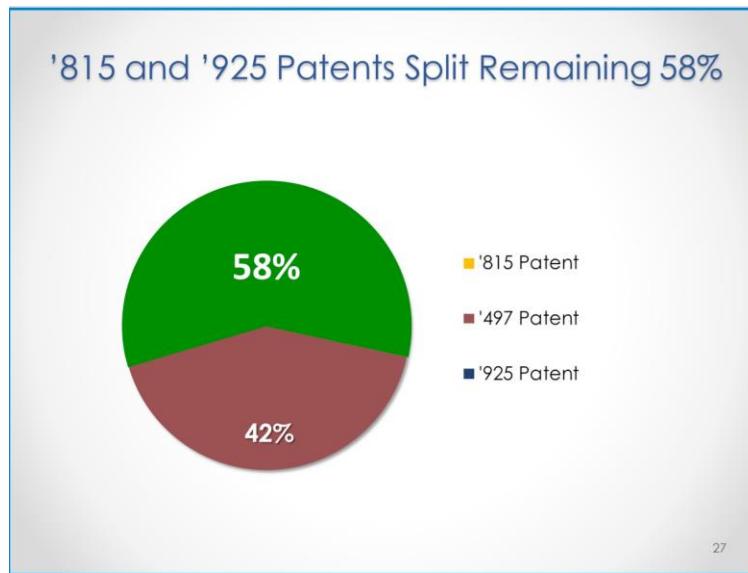
151. Unlike WARF’s expert, WashU’s expert Vincent Thomas did not conduct a financial analysis to determine what money actually flowed from the ’815 patent. Instead, Mr. Thomas came up with four different allocations, all of which he said were “fair”: 27%, 29%, 30%, and 33%. [Thomas 527:4-15, 610:1-611:11.] Not surprising, Mr. Thomas testified that the highest allocation (33%) was the “most fair.” [Thomas 612:9-18.] Mr. Thomas’s arbitrary allocation alone shows no “reasonable certainty” as to the amount of damages.

152. Mr. Thomas’s analysis has several major flaws that were revealed on cross-examination.

153. First, he failed to give sufficient weight to the dominant ’497 compound patent. It was undisputed at trial that the compound patent dominates all other patents and is the most valuable patent. [Cleare 205:1-6; Gulbrandsen 650:8-20, 676:21-677:6; Thomas 595:10-22, 613:24-614:8; Lentz 826:21-827:3; Brandt 359:20-360:3; DeLuca 767:5-24.] In practice, WARF gives the compound patent a majority share of value. [Gulbrandsen 676:8-12, 678:9-23; Thomas 594:17-22.] Mr. Thomas, however, gave more weight to the method-of-use patents (the ’925 controlling use patent and the ’815 patent) as shown in the pie chart below. Specifically, Mr. Thomas allocated 33% to the ’497 compound patent and 66% to method-of-use patents that cover the same FDA-approved indication. [Thomas 614:9-615:15.]



154. Under Mr. Thomas's second scenario, he allocated 42% to the '497 compound patent and 58% to the same method-of-use patents. [Thomas 615:16-616:8.]



155. Mr. Thomas's second flaw is that he failed to allocate anything (or very little) to the Ancillary Patents. He either allocated nothing to the Ancillary Patents (or, in one scenario, 3.9%), contrary to the established practice at WARF and in general in university tech transfer

organizations.<sup>12</sup> [Thomas 594:11-16, 601:10-602:18.] As Dr. Gulbrandsen testified, WARF always allocates some percentage to ancillary patents. [Gulbrandsen 679:5-8.] For other Vitamin D portfolio licenses, WARF allocated 20% to 40%. [Cleare 215:4-9; Thomas 597:6-19; JX16.0031; JX18.034; JX19.027; JX20.011.]

156. Mr. Thomas admitted that he had no experience allocating value in a university tech transfer organization. [Thomas 572:1-13.]

157. Mr. Thomas's third flaw is that he relied heavily in hindsight on events in 2011 and 2012 that WARF could not have known in 1998. Abbott did not list the '815 patent in the Orange Book until 2011. [JX263; Gulbrandsen 701:21-702:3; Thomas 603:3-12.] Mr. Thomas testified that the '815 patent was "listable," but there is no evidence that WARF should have known in 1998 that Abbott would list the '815 patent thirteen years later. [Thomas 603:22-604:6, 605:4-21; Cleare 272:18-273:6.]

158. Abbott did not assert the '815 patent in litigation against generics until 2012. [Thomas 606:16-18; Surber 483:24-484:3.] Mr. Thomas testified that the '815 patent was "assertable," but there is no evidence that WARF would have known in 1998 that the '815 patent would be asserted 14 years later. [Thomas 606:4-15, 606:19-607:14; Cleare 272:18-273:6.]

159. Even if the Court were to find that WARF should have revalued the portfolio, any potential damages are much less than WashU claims. Revaluing after 2011, using Mr. Thomas's assumptions and calculations, results in much lower damages as shown in the below table. [Mulhern 1099:16-1102:9.]

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<sup>12</sup> Mr. Thomas relied on a one-hour conversion with Dr. Cleare to arrive at his opinion regarding the value of the Ancillary Patents. [Thomas 573:11-19.] Dr. Cleare, however, admitted that he lacked any knowledge regarding how Abbott used or valued any of the Ancillary Patents. [Cleare 286:1-287:6, 289:12-290:4.]

Thomas's Proposed Allocation for '815 Patent	Alleged Damages from 1998	After November 2011
14.5%	\$16.4 M	\$3.0 M
27.1%	\$31.6 M	\$5.8 M
29%	\$34.0 M	\$6.2 M
30%	\$35.2 M	\$6.5 M
33%	\$39.2 M	\$7.2 M

## CONCLUSIONS OF LAW

### **I. JURISDICTION AND VENUE**

1. The Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(a)(1).
2. The Court has personal jurisdiction over the parties for the purpose of adjudicating the present dispute, and venue is proper for this action under 28 U.S.C. §§ 1391(b), 1391(c), and 1400(b).

### **II. WASHU'S CLAIMS ARE TIME-BARRED BY WISCONSIN'S SIX-YEAR STATUTE OF LIMITATIONS**

#### **A. The Statute of Limitations Applies to Both of WashU's Claims—Express and Implied**

3. The 1995 IIA should be analyzed under Wisconsin law. [JX1, § 12 (“This Agreement shall be governed by and interpreted—and its performance enforced—in accordance with Wisconsin law . . .”).] WashU agrees that Wisconsin law applies. [D.I. 145 Ex. 11 (WashU’s Proposed COL) ¶ 346.]

4. Wisconsin law provides a six-year statute of limitations for “[a]n action upon any contract, obligation or liability, *express or implied.*” Wis. Stat. § 893.43 (2013).

5. “[I]n an action for breach of contract, the cause of action accrues and the statute of limitations begins to run from the moment the breach occurs. This is true whether or not the facts of the breach are known by the party having the right to the action.” *CLL Assocs. Ltd. P’ship v. Arrowhead Pac. Corp.*, 497 N.W.2d 115, 117 (Wis. 1993) (citations omitted). The “discovery rule” does not apply to breach-of-contract claims. *Id.*

6. WashU alleges breach of contract and breach of implied covenant of good faith and fair dealing (Counts I and II) based solely on WARF’s authority to assign a relative value of

the '815 patent within the paricalcitol portfolio licensed to Abbott. WARF assigned this relative value, one time, per the terms of the 1995 IIA, when it licensed the '815 patent in 1998. Therefore, the limitations period began to run in 1998 for *all* of WashU's contract claims, rendering WashU's entire case statutorily barred by Wisconsin's six-year statute of limitations in 2004. *See* D.I. 130 at 13-14.

7. At trial, WashU treated WARF's statute-of-limitations defense as a mere speed bump in advancing its case. The only evidence WashU points to as allegedly supporting its argument that WARF improperly valued the '815 patent (both in 1998 and 2012) is Abbott's listing of the '815 patent in the Orange Book and asserting the patent in litigation. Those events, however, did not occur until after November 2011, were contemplated by the express terms of the 1995 IIA, and, as explained in greater detail below, are factually and legally irrelevant to whether WashU's claims are time-barred.

**B. Wisconsin's "Periodic Payment" Doctrine Does Not Apply in This Case**

8. WashU concedes that Wisconsin's statute of limitations bars WashU from seeking damages that accrued before April 9, 2007, but argues that, under Wisconsin's "periodic payment" doctrine, it "may assert claims for damages based on each of WARF's annual payments" dated on or after April 9, 2007. [D.I. 145, Ex. 11 (WashU's Proposed FOF/COL ¶ 408.)]

9. The "periodic payment" doctrine, however, does not apply as a matter of law because WashU's claims are not based on continued underpayments that are less than what is required by the terms of the 1995 IIA, and there is no obligation for WARF to revisit or reassign the relative value based either on the parties' intent or the implied covenant of good faith and fair dealing, *see infra* COL ¶¶ 65-81.

**1. The Parties Did Not Intend to Re-evaluate the Relative Value Once It Was Set in 1998**

10. As the Third Circuit previously found, there is no express provision in the 1995 IIA that requires WARF to revisit its assignment of relative value to the '815 patent. *Wash. Univ. v. Wis. Alumni Research Found.*, 703 F. App'x 106, 109 (3d Cir. 2017). The Third Circuit reversed this Court's ruling on summary judgment that Wisconsin's Annual Payment exception to the statute of limitations did not apply based on an issue of disputed material fact: "whether WARF and WashU intended for the '815 Patent would be revalued if it became clear that the value originally assigned to the '815 Patent was insufficient to fairly compensate the University" under the 1995 IIA. *Id.*

11. The evidence at trial established that the parties did not intend for WARF to re-evaluate its assignment of relative value based upon some unspecified event that might happen in the future. *See* FOF 31-34. Instead, WARF's intent to set a fair relative value in the first instance—and only in the first instance—was evidenced by the very first letter from WARF's Mr. Bremer to WashU during negotiation of the 1995 IIA. In this letter, WARF explained that it needed "the flexibility required and allowed under Section 3.A.(iii) [the Relative Value Clause of the 1995 IIA]." [JX39.] In return, WashU remained wholly silent on this issue, without any further negotiation or discussion on the Relative Value Clause, thereby granting WARF the requested flexibility WARF requested. Even Dr. Brandt testified that the Relative Value Clause was clear and "agreeable to [her]." [Brandt 349:4-350:2.] And to this end, both parties were sophisticated enough to have included express language for additional milestone requirements based on a change in the future, if that was their intent. *See S.C. Johnson & Son, Inc. v. Minigrip, LLC*, No. 16-cv-244-jdp, 2017 WL 3503379, at \*4-5 (W.D. Wis. Aug. 15, 2017) (declining to rewrite the parties' contract to include a prohibition on direct competition

between the parties where the express contract did not contain an express provision and “it would have been easy for the parties to articulate what type of competition was prohibited”). The Wisconsin Supreme Court has explained, “the best indication of the intent of the parties is the language of the contract itself.” *Levy v. Levy*, 388 N.W.2d 170, 174-75 (Wis. 1986).

12. Moreover, WashU has failed to prove that there was any customary practice in the technology transfer industry to re-evaluate the relative value based on unforeseen future events. FOF ¶¶ 32-34. Nor was it WARF’s standard practice to re-evaluate the relative value of a patent within a larger Vitamin D patent portfolio because, as Dr. Gulbrandsen testified, re-evaluation is “a logistical nightmare” that would necessarily adversely affect the value of each of the other patents in the portfolio and lead to other potential challenges from other stakeholders also based on some unforeseen change in circumstance. [Gulbrandsen 693:14-694:6]; FOF ¶ 32. And Dr. Cleare’s sole re-evaluation example from a license agreement is not based on customary practice at all, but based on a specific milestone that was agreed to by the parties. It is factually irrelevant to this case, and alone cannot form the basis for finding that re-evaluation is a standard practice in the industry.

13. Instead of re-evaluation, the evidence demonstrated that WARF and other technology transfer offices adopt and implement policies and practices to assign relative value to balance the need for fair and adequate sharing and to allocate license income in a reliable and efficient manner. FOF ¶¶ 76-82. Such is the rationale behind WARF’s blended-theory approach, as WARF explained to WashU in its April 2001 Letter. [JX49]; FOF ¶¶ 82, 110.

14. WARF had no obligation to revalue the ’815 patent at any point after its initial valuation of that patent and the other patents in the Abbott portfolio in 1998. The record in this case is completely devoid of how Abbott did or did not use the other Ancillary Patents that were

not Orange Book eligible. Dr. Cleare admitted on cross-examination that he did not know how Abbott did or did not use many of the patents, most notably the patents covering the manufacture of Zemplar. [Cleare 286:13-287:6, 289:12-18.]

**2. WashU Cannot Establish That WARF Separately Breached the 1995 IIA Each Year from 2007-2017 Based on Its 1998 Allegations**

15. WashU argues that WARF separately breached the 1995 IIA at some point (it is not exactly clear what they allege as an actual breach) after 2007 (six years back from the tolling agreement) under the periodic-payment doctrine because WARF calculated the royalty payment each year. [Jacobs 1148:3-6; D.I. 145, Ex. 11 (WashU's Proposed COL) ¶¶ 405-407.] But that cannot be right because it is undisputed that WARF's assignment of relative value of .968% in 1998 controlled each and every single payment that WashU has ever received. WARF applied the exact same formula, based on the exact same relative value, every year from 1998 to 2017. The *only* variable to the calculation is the amount of money received from Abbott. There is no "independent" calculation based on WARF's discretion. WashU does not allege that WARF ever artificially reduced the gross royalty amount that went into the calculation or that it ever artificially inflated the administrative costs that went into the calculation. It also does not allege that WARF ever made a calculation error, skimmed off the top, withheld or missed a payment, or sent WashU anything less than a properly calculated amount.

16. Under Wisconsin law, contracts involving periodic payments where all periodic payments stem from a purportedly erroneous calculation *set in the first instance* are not subject to the "continuing contract" rule. *See Messner Manor Assocs. v. Wis. Hous. & Econ. Dev. Auth.*, 555 N.W.2d 156, 159-60 (Wis. Ct. App. 1996). In *Messner Manor*, the court determined that the six-year statute of limitations barred the plaintiff's breach-of-contract claim initiated in

May 1990, where the plaintiff made *all* of its monthly housing payments based upon a purportedly excessive interest rate fixed at closing in September 1978. *Id.* at 160.<sup>13</sup>

17. While WashU now relies on events in 2008 and beyond, it has only ever taken issue with the amounts WARF paid based on the relative value that WARF set in 1998 and explained to WashU in 2001. [See, e.g., D.I. 145, Ex. 11 (WashU's Proposed COL) ¶ 420 (identifying the 2008 Stoveken Email, the 2011 Orange Book listing, and 2012 assertion of the '815 patent in litigation as alleged "breaches" that establish "it should have been more obvious to WARF that its relative valuation was incorrect").] WashU's position here is inconsistent. If WashU concedes that WARF's original valuation in 1998 was fair, then WashU must prove that WARF had a duty to re-evaluate the relative value based on unforeseen future events—something WashU has failed to prove, *see* COL ¶¶ 10-14. On the other hand, by alleging that unforeseen events in 2011 and 2012 establish that WARF's *original* valuation in 1998 was somehow wrong, then WashU's allegations are completely time-barred by Wisconsin's six-year statute of limitations.<sup>14</sup>

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<sup>13</sup> WashU's reliance on *Jahn Transfer* to criticize the holding in *Messner Manor* is also misplaced. *Jahn Transfer, Inc. v. Horizon (H&S) Freightways, Inc.*, 819 N.W.2d 563, 2012 Wis. App. LEXIS 484, at \*4-7 (Wis. Ct. App. 2012) (unpublished). In *Jahn Transfer*, the court attempted to distinguish *Messner Manor* as affirming dismissal on the basis that there was no breach, explaining that the statement in *Messner Manor* that the breach-of-contract claim was "time barred" was a "drafting error." *Jahn Transfer*, 2012 Wis. App. LEXIS 484, at \*5-6. *Jahn Transfer*, however, is not precedent, and the court lacked the authority to modify any portion of *Messner Manor*, even under the guise of "clarifying" the law. *See* Wis. Stat. § 809.23(3)(b); *Cook v. Cook*, 560 N.W.2d 246, 255-56 (Wis. 1997) ("[O]nly the supreme court, the highest court in the state, has the power to overrule, modify, or withdraw language from a published opinion of the court of appeals.").

<sup>14</sup> Under Wisconsin law, "[i]f a single total breach occurs, the right to bring an action accrues at that time and the statute of limitations begins to run." *Segall v. Hurwitz*, 339 N.W.2d 333, 343 (Wis. Ct. App. 1983); *see also* D.I. 130 at 14 ("WashU's claim for breach of contract is based on WARF's assignment of relative value in 1998, which governed all subsequent annual payments, the statute of limitations began to run in 1998, and WashU's breach of contract claim expired in

18. For WashU to succeed on a “periodic payment” excuse, it would have to show that WARF was required by the 1995 IIA to *recalculate* the relative value of the ’815 patent every year in order for there to be an alleged underpayment. WashU does not—because it cannot—make this claim.

19. All of the “periodic payment” cases WashU relies on are not relevant to this case because they all involve separate distinct breaches that are not time-barred. *See Segall*, 339 N.W.2d at 343 (“The injured party may assert a claim for damages from the date of the first breach within the period of limitation.”).

20. In *Jahn Transfer*, an unpublished decision by the Wisconsin Court of Appeals, the court held that the defendant partially breached the parties’ revenue-splitting agreement each time he took a cut off the top of a customer’s payment. 2012 Wis. App. LEXIS 484, at \*3, 6.

21. In *Policeman’s Annuity & Benefit Fund v. City of Milwaukee*, the court held that the defendant underpaid the contracted annuities by mistakenly failing to make the required contributions under the collective-bargaining agreement. 630 N.W.2d 236, 242-43 (Wis. Ct. App. 2001).

22. In *Jensen v. Janesville Sand & Gravel Co.*, the court held that “the company’s repudiation of its obligation to pay [an employee] an annual pension did not result in a total breach requiring him to commence this action within six years from the date of repudiation.” 415 N.W.2d 559, 561-62 (Wis. Ct. App. 1987).

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2004.”). Therefore, WashU’s breach-of-contract allegations based on WARF’s 1998 assignment of relative value are time-barred.

23. In *Welter v. City of Milwaukee*, the plaintiff firefighters received “a pension installment payment that [was] less than that required by contract.” 571 N.W.2d 459, 465 (Wis. Ct. App. 1997).

24. In *Butler v. Kirby*, the plaintiff employee was underpaid each month pursuant to his oral employment agreement. 10 N.W. 373, 374-75 (Wis. 1881) (“It is very evident, from the plaintiff’s own statements, that he worked by the month, and that his wages became due at the end of each month, and that at least eight dollars per month of each month’s wages remained unpaid.”).

25. Here, it is undisputed that WARF never underpaid WashU as compared to the payment WARF said it would make based on the relative value assigned to the ’815 patent in 1998.

26. Not one of the cases WashU cites allows a party to sue for breaches occurring outside the limitations period (in this case, 2004) absent the application of equitable estoppel. While WashU conveniently argues that its claims are not based on a “total breach” occurring in 1998, that is exactly what its claims are based on, as they have admitted in the past. [D.I. 108 at 16; JX337.0013.] WashU’s argument is merely semantics because WashU does not point to any *other* breach, and its claims are not based on anything else but WARF’s decision in 1998 to value the ’815 patent equally with thirty other patents. Therefore, there can be no question that the statute of limitations began to run in 1998. *See In re Rinaldi*, 487 B.R. 516, 538 (Bankr. E.D. Wis. 2013) (holding that because the claims stemmed from an event more than six years before and “not some subsequent breach,” they were barred by the statute of limitations). The 2007-2016 time frame asserted by WashU is therefore irrelevant, and its claims are time-barred.

27. Other courts have consistently refused to apply the continuing-contract doctrine in cases where, like here, the plaintiff argues that there are subsequent “underpayments” stemming from an otherwise time-barred breach. *See, e.g., McNamara v. City of Nashua*, 629 F.3d 92, 97 (1st Cir. 2011) (“That the wrong (if any) had *consequences* that endure to the present does not make the violation a continuing one.”); *R.C. Beeson, Inc. v. Coca Cola Co.*, 337 F. App’x 241, 245 (3d Cir. 2009) (“While the subsequent underpayments put Beeson on notice of the breach and were part of the fallout from it, they did not give Beeson the opportunity to delay action on its claim. . . . Allowing Beeson to pursue its claims after standing idle for over a decade would undermine New Jersey’s statute of limitations.”); *Muñiz Rivera v. United States*, 204 F. Supp. 2d 305, 315 (D.P.R. 2002) (“A continuing violation occurs when there is a series of continual unlawful acts, *not* when there are merely continual harmful effects from an original unlawful act.”).

### **III. WASHU FAILED TO ESTABLISH EQUITABLE ESTOPPEL AS A DEFENSE TO THE STATUTE OF LIMITATIONS**

#### **A. Legal Standard**

28. “By definition, equitable estoppel is based upon the fraudulent or other wrongful conduct on the part of the party asserting the statute of limitations and upon the detrimental reliance on such fraudulent or wrongful conduct by the aggrieved party.” *Hester v. Williams*, 345 N.W.2d 426, 431 (Wis. 1984). For a court to invoke equitable estoppel, “a party’s reliance on another’s conduct must be reasonable.” *Johnson v. Johnson*, 508 N.W.2d 19, 23 (Wis. Ct. App. 1993). “Proof of estoppel must be clear, satisfactory and convincing and is not to rest on mere inference or conjecture.” *Id.* at 22 (citing *Gonzalez v. Teskey*, 465 N.W.2d 525, 530 (Wis. Ct. App. 1990)).

29. “[T]he test of whether a party should be estopped from asserting the statute of limitations [i]s ‘whether the conduct and representations of [the party] were so unfair and misleading as to outbalance the public’s interest in setting a limitation on bringing actions.’” *Hester*, 345 N.W.2d at 431 (quoting *State ex rel. Susedik v. Knutson*, 191 N.W.2d 23, 26 (Wis. 1971)). Here, WashU has failed to set forth clear and convincing evidence for any one of the following elements of the doctrine, where all are required: (1) *fraud or inequitable conduct* by the defendant; (2) failure of the plaintiff to commence an action within the statutory period because of *reliance* on the wrongful conduct; and (3) the alleged acts or representations must have occurred *before* the expiration of the limitation period. *See, e.g., id.; Johnson*, 508 N.W.2d at 22 (citing *Knutson*, 191 N.W.2d at 25).

## **B. WashU Fails to Meet Its High Burden**

### **1. The April 2001 Letter**

30. WashU’s primary piece of evidence is WARF’s April 2001 Letter [JX49]. But that letter when it was written, ten years before the ’815 patent was listed in the Orange Book or used by Abbott, is not evidence of fraudulent concealment. Nothing in that letter was either fraudulent or concealed. FOF ¶¶ 135-137. Just the opposite, WARF explained to WashU its allocation policies and 0.968 percent relative value assigned to the ’815 patent. It told WashU that the ’815 patent shared an equal value with 30 other patents in the Ancillary Patent group. It told WashU that the compound patents received 70% of the relative value. It told WashU how to back-calculate the amount of royalties that WARF was earning as compared to WashU. [Surber 466:15-20]; FOF ¶ 110.

31. It is not WARF’s fault that WashU never followed up on WARF’s detailed letter with any further questions or concerns. FOF ¶¶ 111, 117-120. There is no evidence that WashU ever asked for the 1998 WARF-Abbott License in 2001, or at any time thereafter during the

limitations period (because it was not in existence when they asked the first time in 1998 by email, and there is no evidence that anyone at WashU in 2001 through 2004 actually had knowledge of that 1998 email). FOF ¶¶ 129-132, 135. WashU never asked for, or even hinted at wanting, the other patents in the 1998 WARF-Abbott License until eight years after the limitations period had expired. [Surber 463:21-464:2.] At bottom, there is no evidence that the statements in the 2001 Letter were misleading in any way, FOF ¶¶ 135-137, let alone so misleading as to outbalance the public's interest in setting a time limit on bringing actions.

32. Moreover, there was no reliance by WashU. WashU presented no contemporaneous evidence of its response, if any, after it received the April 2001 Letter, including any belief that it formed with regard to that letter, and therefore WashU cannot prove that it failed to file suit within the limitations because of any reasonable reliance on WARF's statements. Mr. Surber's litigation-driven opinions in 2012, no matter how strong, are not evidence of reliance. FOF ¶¶ 126-127.

## **2. The 1998 Email Regarding a License Agreement That Did Not Exist**

33. WashU also relies on a May 1998 email [JX46], in which WARF did not send them the requested license agreement, because, as WashU now asserts, WARF misrepresented confidentiality provisions. The evidence at trial shows, however, three things: (1) WARF in the email unequivocally and truthfully told them that the '815 patent had not yet been licensed; (2) there was no license agreement pertaining to the '815 patent for WARF to give them in May 1998 because it was not executed until July of that year; and (3) in the last sentence of the email, WARF stated, "that I am sure your office has the same restrictions," which told WashU that WARF had a standard policy not to share license agreements with inter-institutional agreement partners. This was confirmed by WARF's Mr. Gulbrandsen along with a very clear explanation for WARF's long-standing policy. FOF ¶ 130.

### **3. WARF's Efforts to License the 815 Patent: "Directly Supports"**

34. In 1996, WARF tried to license the parties' joint technology by writing a letter to Abbott to take a license. [JX42.] Given that the parties' patent application (the '815 patent did not issue until 1997) and its draft claims related to a method of using paricalcitol, everyone agrees that Abbott was the "logical choice" as a potential licensee [Cleare 259:4-14]—by this time, Abbott's paricalcitol drug development was well underway with clinical testing in humans. Abbott never responded to WARF's initial request to license the joint technology.

35. Twenty-one months passed without a response from Abbott. WARF tried again to fulfill its obligations under the IIA to commercialize the joint technology. WARF wrote Abbott again, this time stating that the '815 patent "directly supports" the Zemplar drug product. [JX47.] In an attempt to breathe life into "directly supports," WashU now argues that, at the time WARF wrote the letter, WARF knew how Abbott was going to use the patent 13 years later when Abbott listed it in the Orange Book. That defies common sense.

36. At trial, there was no testimony from any witness with first-hand knowledge of what "directly supports" in WARF's 1998 letter to Abbott actually meant. FOF ¶ 133. There was no testimony from either Ms. Kirkpatrick—who wrote the letter—or Ms. Mershimer from Abbott—who received it. There were no attachments that prove that WARF ever conducted the patent-specific evaluation as WashU contends WARF must have done.<sup>15</sup>

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<sup>15</sup> It is somewhat astonishing how WashU has tried to turn the tables on WARF by parsing two words in a 1998 letter in complete hindsight and with no reasoned basis to do so, when through its letters to Abbott, WARF was only trying to commercialize/license the '815 patent, as it was obligated to try to do under the express terms of the IIA. And WARF succeeded in its efforts to WashU's benefit. Had WARF made best efforts but then given up after 21 months of silence and no response from Abbott, and ended up never having licensed the '815 patent at all, then WashU would have received nothing at all under the 1995 IIA.

37. The only persons who purported to understand the meaning of this phrase were WashU's attorneys. Even WashU's expert Dr. Cleare said that the letter didn't say "cover" or "infringes" or show any evidence of conducting a patent-specific evaluation. [Cleare 265:18-266:8.] Dr. Gulbrandsen, who was at WARF at the time and supervised Ms. Kirkpatrick, testified that he did not know what she meant. [Gulbrandsen 663:11-16.] But he did know that it was not WARF's practice to conduct a claim-by-claim analysis, because again, WARF did not know how Abbott would or would not use the patent. FOF ¶¶ 81, 83, 84. In hindsight, that much is true, because Abbott did not use the patent for more than 13 years.

#### **4. WashU Did Nothing on Relative Value for a Decade**

38. In the end, more than a decade went by after the April 2001 letter without any questions from WashU about the 0.968 percent relative value that the '815 patent shared with 30 other WARF-owned patents in the Ancillary Patent group. FOF ¶¶ 110-112. Over that decade, the evidence showed that both Dr. Slatopolsky and Mr. Kratochvil, who was responsible for the IIA during the 2000s, knew how much money WashU was receiving by 2001 and were pleased with the amount of royalties received prior to 2012. FOF ¶ 127.

39. WashU ultimately filed this lawsuit in 2013 based on the same perceived lack of information it now contends it had in 2001, namely, no license agreement or list of patent numbers. WashU cannot credibly contend "misrepresentations" to its detriment, or that it was somehow kept "in the dark" by WARF, when the only other events it relies on after 2001 were all publicly known (i.e., the claims of the '815 patent, Zemplar's label, Zemplar's Orange Book listings, and the assertion of WARF's patents in Hatch-Waxman litigation). *KDC Foods, Inc. v. Gray, Plant, Mooty, Mooty & Bennett, P.A.*, 763 F.3d 743, 753-54 (7th Cir. 2014) (applying Wisconsin law) (finding plaintiff's failure to commence its claim was not a result of reliance on

defendants' act where plaintiff was able to file its original complaint before it was aware of additional documents that defendants allegedly intentionally withheld).

40. While WashU now argues that the identity of the other patents was crucial to knowing it had a claim, WashU offers no explanation why it never asked any questions or requested that information from WARF after learning in 2001 that WARF assigned a relative value of 0.968 percent to all 31 "Ancillary Patents" in the portfolio, why it did no investigation of publicly available patent and regulatory information, or why it did not file suit within the limitations period to gain access to the same information.

41. To the extent that WashU relies on the testimony of WARF's expert James Severson that WashU would need to know "where their patents sat in relationship to other patents" [Tr. 31:6-23] that were licensed, that reliance is misplaced. There is no evidence that WashU asked either before or after the 2001 Letter for the identities of the patents. Therefore, there is no evidence that this information was "concealed" from WashU. To the contrary, the 2001 Letter told WashU that there were 31 Ancillary Patents. [JX49.] As Dr. Severson testified, "WashU also had an obligation to further pursue their demands and to ask additional -- for additional information. That was always on the table." [Severson 989:12-22.] WashU cites no legal authority to support its proposition that WARF could somehow "fraudulently conceal" information in 2001 that WashU never asked for.<sup>16</sup>

42. WashU does not dispute that it received a royalty report every year that detailed WARF's calculation of WashU's royalty and allowed WashU to calculate WARF's royalties

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<sup>16</sup> And, contrary to WashU's argument, WARF's position in 2013 not to identify the identities of the patents after receiving a prelitigation letter from WashU's outside counsel is not evidence that WARF would not have provided that information back in 2001 in a collegial discussion between the two offices.

from Abbott. FOF ¶¶ 97-103, 119. Armed with the knowledge of the FDA's approval of Zemplar in 1998 and the amount of royalties received by WARF, WashU could have investigated the alleged use of the '815 patent by examining the patents listed in the Orange Book and the approved package insert for Zemplar. FOF ¶¶ 111, 119; *see Jackson v. Rockford Hous. Auth.*, 213 F.3d 389, 394 (7th Cir. 2000) ("[W]e have refused to grant equitable estoppel when the plaintiff retained the ability, notwithstanding the defendant's delay or resistance, to obtain information necessary to pursue [its] claim."); *Wash. Univ.*, 703 F. App'x at 110 (citing *Jackson*, 213 F.3d at 394).

43. WashU also cannot legally contend under Wisconsin law that WARF should be equitably estopped based on *any* other events occurring after 2004.<sup>17</sup> *Johnson*, 508 N.W.2d at 22 (citing *Knutson*, 191 N.W.2d at 25 (holding that the only acts and representations the court may consider in deciding whether to apply estoppel are those which occurred within the limitations period)).

## **5. WashU's Cited Authority Is Factually Distinguishable**

44. The cases cited by WashU are inapposite. In *Policeman's Annuity*, the court found that the defendant was responsible to catch its own mistake in failing to make promised contributions to an annuity fund because the defendant had two representatives on the board to ensure proper payments to the fund, and had amended its charter so that it would not need to certify as to the annual amounts owed. 630 N.W.2d at 243. WARF does not have these or similar contractual obligations, and WashU cannot dispute that by 2001 it knew the relative

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<sup>17</sup> Those events include WashU's allegations regarding (1) Mark Stoveken's 2008 analysis of expiration dates in the Abbott patent portfolio; (2) Abbott's listing the '815 patent in the Orange Book in late 2011 and subsequent assertion of the patent in litigation; (3) WARF's statements in complaints and settlement agreements that it was the owner of the '815 patent; (4) WARF's statements in its February 2013 prelitigation letter to WashU; and (5) Abbott's and WARF's expert reports submitted in the *Hospira* litigation.

value WARF assigned to the '815 patent. WashU also does not dispute that it received a royalty report every year that detailed WARF's calculation of WashU's royalty, and allowed WashU to back-calculate the royalty to determine WARF's royalties from Abbott. Even knowing this information year after year, WashU never raised any question, concern, or complaint to WARF.

45. In *Barry Aviation Inc. v. Land O'Lakes Municipal Airport Commission*, 377 F.3d 682 (7th Cir. 2004), the court found that the plaintiff "conceal[ed] evidence from the plaintiff that [it] needed in order to determine that [it] had a claim," *id.* at 689-90 (alterations in original) (citations omitted). Here, WashU admits that it received no more information from WARF prior to filing this suit in 2013 than it received in 2001. Moreover, WARF has not concealed any material evidence to WashU's purported claim—WashU cannot reasonably argue that WARF "conceal[ed]" the 1998 WARF-Abbott License because WashU asked for it in 1998 before it was even executed. FOF ¶ 129. And there is no evidence that WashU ever asked for the identities of the 31 Ancillary Patents at any point prior to 2012. [Surber 463:20-464:2; Severson 970:10-13.]

46. Accordingly, there is no action, inaction, or representation by WARF that prevented WashU from timely filing suit, and WARF is not equitably estopped from asserting its statute-of-limitations defense.

#### **IV. WASHU FAILED TO ESTABLISH BREACH OF CONTRACT—EXPRESS OR IMPLIED**

##### **A. No Express Breach**

###### **1. Legal Standard**

47. "Under Wisconsin law, a plaintiff claiming breach of contract has the burden of proving by a preponderance of the evidence that a contract exists, that the defendant's actions violate the express language of the contract, and that the defendant's breach is material and

results or will result in injury.” *Walgreen Co. v. Sara Creek Prop. Co.*, 775 F. Supp. 1192, 1195 (E.D. Wis. 1991).

48. Under Wisconsin law, “[t]he interpretation of an unambiguous contract presents a question of law.” *Town Bank v. City Real Estate Dev., LLC*, 793 N.W.2d 476, 483 (Wis. 2010) (citing *Admanco, Inc. v. 700 Stanton Drive, LLC*, 2010 WI 76, ¶ 15, 786 N.W.2d 759, 765 (Wis. 2010)). “When construing contracts that [are] freely entered into, [the Wisconsin court’s] goal ‘is to ascertain the true intentions of the parties as expressed by the contractual language.’” *Id.* at 484 (citations omitted). “If the contract is unambiguous, [the Wisconsin court’s] attempt to determine the parties’ intent ends with the four corners of the contract, without consideration of extrinsic evidence.” *Id.* (citation omitted). The court construes the contract language according to its plain or ordinary meaning.<sup>18</sup> *Id.*

## **2. WARF Did Not Expressly Breach the 1995 IIA**

49. The evidence showed that WARF’s assignment of relative value to the patents, including the ’815 patent, in the licensed portfolio in 1998 was not “arbitrary” or “unfair,” in view of the facts known in 1998—the ’815 patent was added to a pre-existing 1993 license agreement with Abbott after the licensed field of use was expanded to “all human therapeutics” and Abbott obtained FDA approval and began selling Zemplar. FOF ¶¶ 46, 48, 49. WashU attacked WARF’s assignment of relative value based on unforeseen events in Abbott’s twenty-year marketing of Zemplar, including generic litigation challenges and the use of patents by Abbott within the licensed portfolio for which WARF had no control, no way to know, and no way to predict. WARF’s assignment of relative value under its blended approach, however, remained fair even in view of these unforeseen events. FOF ¶¶ 149-150.

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<sup>18</sup> WashU has previously argued in its Summary Judgment motion that the terms of the 1995 IIA are unambiguous. D.I. 105 at 12 n.3.

50. The evidence also showed that WARF did not have the manpower or expertise to always determine how its licensees are using patents that are not compound or controlling use patents, and accordingly, WARF acted based on its long-standing practices of allocating greater value to the compound patent when it set the relative value in 1998. FOF ¶¶ 74-88. There was no evidence to support WashU's argument that WARF engaged in "self-dealing" by giving more value to the compound patent family, since every witness testified that the compound patent family was the most valuable. Without knowing exactly how Abbott would eventually use the '815 patent (and the other Ancillary Patents), assigning it a relative value that was equal to the other WARF-owned Ancillary Patents in the portfolio was not self-dealing either. FOF ¶ 76, 85.

51. WARF performed every one of its obligations under the 1995 IIA. Nonetheless, WashU argues it was treated it "shabbily." WashU failed to present any contemporaneous evidence whatsoever. There was no testimony from WashU's Office of Technology Management, either in documents or testimony, that WARF was not collegial or did not treat it properly. WashU's arguments rest on a hindsight critique of a couple of discrete events during the course of a twenty-year relationship.

52. Contrary to WashU's arguments, the contemporaneous evidence established that WARF regularly corresponded with WashU and always answered WashU's questions.

53. From the outset, WARF treated WashU fairly and kept them apprised. It started on July 21, 1995, when Mr. Bremer included a copy of the '815 patent application in his initial letter to Dr. Brandt. [JX39.]

54. On September 1996, WARF consulted with WashU regarding its intent to file foreign applications. [JX172.]

55. On January 21, 1997, WARF wrote WashU about its foreign filing intentions and provided a foreign patent cost estimate to see if WashU would be interested in patent protection outside the United States. [JX43.]

56. On September 19, 1997, WARF informed WashU that the '815 patent had issued in the United States and enclosed a copy of the issued patent and updated foreign filing prosecution and licensing activity. [JX44.] In that letter, the WARF licensing associate stated, "I am actively pursuing several leads in licensing this technology and will provide you periodic updates on my progress." [JX44.]

57. On May 13, 1998, WARF informed WashU via facsimile that it was "working on incorporating the DeLuca/Slatopolsky technology . . . as an amendment to an existing license agreement." [JX45.]

58. On October 26, 1998, WARF informed WashU that the '815 patent had been successfully added to the "Abbott License Agreement this summer," and that "Abbott Laboratories received approval of Zemplar® in April 1998 and they subsequently launched this product in late May 1998." [JX48.]

59. On November 25, 1998, WARF provided WashU with its first royalty report and payment, explaining that the disbursement is "based on the first royalty revenue received from Abbott Laboratories for their product Zemplar®." [JX21.] Subsequent royalty reports and checks followed every year. FOF ¶¶ 100-102.

60. Every one of these correspondence ended by stating that if WashU had any questions or concerns to please contact WARF. FOF ¶ 103. And the evidence shows that every time WashU asked a question from 1995 through this dispute, WARF promptly responded to

WashU. FOF ¶ 96. WashU has not identified a single instance where WARF failed to promptly and collegially respond to WashU's questions to the best of its abilities.

61. It is undisputed that WARF sent WashU a copy of the '815 patent, licensed the '815 patent for commercial development as part of the Abbott patent portfolio for the mutual benefit of the parties, assigned the '815 patent a relative value within that portfolio consistent with its policies and practices, and paid WashU its share of the royalties per the 1995 IIA, which amounted to approximately \$1.5 million (present value). FOF ¶¶ 74-88, 93, 95, 149. The parties did not negotiate for anything more, and WARF has performed each one of its obligations as the senior party to the IIA. WashU does not allege that WARF ever made a calculation error, skimmed money off the top, withheld or missed a payment, or sent WashU anything less than a properly calculated amount under the assigned relative value.

62. Moreover, the controlling Relative Value Clause at issue was specifically negotiated by the parties after WARF informed WashU of the complex backdrop of Dr. DeLuca's Vitamin D portfolios and the importance of the provision. Dr. Brandt testified that the Relative Value Clause was clear and "agreeable to [her]." [Brandt 349:4-350:2.] Dr. Brandt did not negotiate for additional information sharing as Dr. Severson testified is commonly done during IIA negotiations. [Severson 930:17-21.] Accordingly, there is no provision in the IIA that requires WARF to seek input from WashU when determining relative value, to work with WashU to set the relative value for the '815 patent, or to even inform WashU of the reasoning behind the relative value that it was authorized to set.

63. WashU's reliance on the Mutual Benefit and Cooperation Clauses is misplaced, for WashU acknowledges that, when it comes to setting relative value for the '815 patent, the

parties are not as aligned as they might be in patent prosecution or other contractual matters.<sup>19</sup>

But what matters here is that WashU granted WARF the authority to set the relative value, and WARF did so based on long-standing practices—which by definition are not arbitrary—and, moreover, WARF views these standard practices as fair. *See COL ¶¶ 70-79.*

64. WashU argues that the 2008 Stoveken Email, Abbott’s 2011 Orange Book listing, and the 2012 assertion of the ’815 patent in litigation establish that “it should have been more obvious to WARF that its relative valuation was incorrect.” [D.I. 154, Ex. 11 (WashU’s Proposed COL) ¶ 420.] But these events cannot establish a breach of the express terms of the 1995 IIA. As the Third Circuit found, there is no express provision in the 1995 IIA requiring WARF to revisit its original allocation of relative value. *Wash. Univ.*, 703 F. App’x at 108-09. WARF cannot be faulted for failing to read a crystal ball and predict such events initiated by Abbott more than a decade later.

## B. No Implied Breach

### 1. Legal Standard

65. “Wisconsin law does recognize that ‘[e]very contract implies good faith and fair dealing between the parties to it, and a duty of cooperation on the part of both parties.’” *Super Valu Stores, Inc. v. D-Mart Food Stores, Inc.*, 431 N.W.2d 721, 726 (Wis. Ct. App. 1988) (alteration in original) (citation omitted) (finding no breach of the covenant of good faith where, however, “a contracting party complains of acts of the other party which are specifically authorized in their agreement”); *see also Wash. Univ.*, 703 F. App’x at 109 (agreeing that the 1995 IIA created an obligation of good faith and fair dealing).

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<sup>19</sup> WashU’s claim that WARF owed it a fiduciary duty under the IIA was rejected during summary judgment, and WashU did not appeal that finding. D.I. 130 at 22-24.

66. “[T]he rule implying a covenant of good-faith conduct in all contracts is intended as a guarantee against ‘arbitrary or unreasonable conduct’ by a party.” *Foseid v. State Bank of Cross Plains*, 541 N.W.2d 203, 213 (Wis. Ct. App. 1995) (citing Wis. JI-Civil 3044) (identifying the following types of bad faith: “evasion of the spirit of the bargain, lack of diligence and slacking off, willful rendering of imperfect performance, abuse of a power to specify terms, and interference with or failure to cooperate in the other party’s performance” (quoting Restatement (Second) of Contracts § 205 cmt. d (1981)); *see also Schaller v. Marine Nat’l Bank of Neenah*, 388 N.W.2d 645, 651 (Wis. Ct. App. 1986) (“Good faith has also been characterized as ‘decency, fairness or reasonableness in performance or enforcement’ of a contract.” (citation omitted)).

67. Moreover, as the *Gilson* case relied on by WashU explains, “the duty of good faith does not provide an independent source of obligations from which a court may draw to reform agreements because they appear with the benefit of hindsight to be inequitable or unreasonable.” 2005 U.S. Dist. LEXIS 16825, at \*5; *see also Wis. Nat. Gas Co. v. Gabe’s Constr. Co.*, 582 N.W.2d 118, 121 (Wis. Ct. App. 1998) (“[T]he covenant of good faith and fair dealing that is implied in all contracts ‘cannot override’ a contract’s ‘express’ terms . . . .” (citation omitted)); *Wash. Univ.*, 703 F. App’x at 109 (“A party cannot use the covenant to undo express terms of a contract.”).

68. Despite having “vaguely moralistic overtones,” the implied covenant of good faith and fair dealing also does not mean that a party is “obliged to become an altruist toward the other party” and relax contract terms. *Mkt. St. Assocs. Ltd. P’ship v. Frey*, 941 F.2d 588, 593-95 (7th Cir. 1991) (applying Wisconsin law) (“‘Good faith’ is a compact reference to an implied undertaking not to take opportunistic advantage in a way that could not have been contemplated

at the time of drafting, and which therefore was not resolved explicitly by the parties.” (citation omitted)).

69. “The plaintiff bears the burden of showing a breach of good faith and fair dealing.” *Betco Corp. v. Peacock*, 876 F.3d 306, 310 (7th Cir. 2017) (applying Wisconsin law).

**2. WARF’s Assignment of Relative Value Was Based on Long-Standing Practices, Was Made in Good Faith, and Fairly Compensated WashU**

70. There is no evidence establishing that WARF exercised any rights under the 1995 IIA in an unfair, arbitrary, unreasonable, or capricious way or with the objective of preventing WashU from receiving its reasonably expected fruits under the contract. Indeed, the opposite is true—WARF’s assignment of a relative value to the ’815 patent, made within WARF’s granted authority, was based on long-standing practices that WARF believes to be fair, and there is no evidence of financial injury to WashU, as it has already been paid more than its share of the incremental royalties attributable to the ’815 patent. *See* FOF ¶¶ 74-88, 146-150. Accordingly, WashU received all of its reasonably expected benefits under the 1995 IIA.

71. As discussed above, it is undisputed that WARF had a very specific practice in place—i.e., placing a higher value on the dominating compound patent families and then setting an equal share for the remaining patents—when it assigned relative values to all licensed patents within the 1998 WARF-Abbott License. FOF ¶¶ 79-83, 85-87. WashU also does not dispute that WARF has followed this same practice when it assigned relative values to patents in Dr. DeLuca’s other Vitamin D portfolios. As Dr. Cleare acknowledged, WARF has previously allocated the compound patent family relative values of both 60% and 80%, which he admits are close to the 70% relative value allocated for the compound patent family here, with the remainder allocated to the Ancillary Patents evenly. [Cleare 215:4-10.] Accordingly, WARF

had an established process to assign relative values to the DeLuca patents, and that is a practice which is not “arbitrary.”

72. Here, WARF acted consistently with those practices when it expressly told WashU in 1995—and again in 2001—that it did not determine how its potential licensees may or may not use the WARF licensed patents. FOF ¶ 84. As Dr. Gulbrandsen testified, WARF abided by its standard practice when it allocated 70 percent of total revenue to the ’497 compound patent family and 30 percent of total revenue equally to the 31 nonexclusively licensed Ancillary Patents. FOF ¶ 79-83, 85-87. As an “Ancillary Patent,” the ’815 patent was allocated an equal 0.97 percent (30/31) share of licensed proceeds, as was every other WARF-owned Ancillary Patent. FOF ¶ 85.

73. Besides the classification into core patents and ancillary patents, Dr. Gulbrandsen testified that WARF did not as a matter of practice make patent-specific valuation decisions or conduct any infringement analysis for any of its licensed patents. FOF ¶ 81. WARF’s expert Dr. Severson further testified that WARF’s practice was reasonable and consistent with the way that other technology transfer offices approached patent valuation. [Severson 952:9-954:3, 955:8-19.]

74. The undisputed evidence shows that WARF did not engage in arbitrary self-dealing, or misrepresent or conceal facts about WARF’s relative valuation of the ’815 patent. WARF told WashU exactly *what* it was doing with the ’815 patent, *how* it was doing it, and *why*, both before and after WARF set the relative value in 1998.

75. WARF’s actions are in stark contrast to the potential “bad faith” breaches in the cases relied on by WashU. In *Gilson*, the parties were competitors, and the defendant had the duty to promote plaintiff’s pipettes as part of the parties’ exclusive dealing agreement. 2005

U.S. Dist. LEXIS 16825, at \*5. Instead, the defendant breached the agreement “by attempting to convince customers to purchase [defendant’s] pipettes instead of [plaintiff’s] pipettes or by replacing customers’ [plaintiff’s] pipettes with [defendant’s] pipettes.” *Id.* at \*7-9. Likewise, the “dispositive question” in *Market Street Associates* was “simply whether [the plaintiff] tried to trick [the defendant]” into selling a leased property at the bargain price set forth in the contract. 941 F.2d at 596. In *Wisconsin Natural Gas Co.*, the plaintiff “assur[ed]” the defendant “in word and deed” that it would not seek to hold the defendant liable under the contract’s indemnification clause, and then later brought suit after receiving a jury verdict finding the plaintiff liable for damages. 582 N.W.2d at 122.

76. Finally, there is no evidence that WARF’s assignment of relative value meets any of the laundry list of bad-faith actions identified by the Seventh Circuit in *Designer Direct, Inc. v. DeForest Redevelopment Authority*, 313 F.3d 1036 (7th Cir. 2002). WARF has not evaded the spirit of the bargain with WashU, acted with a lack of diligence, willfully rendered an imperfect performance, abused a power to specify terms, or interfered with or failed to cooperate with WashU’s performance. *Id.* at 1046-47.

77. Here, there is no evidence that WARF acted in bad faith or denied WashU the benefit of the original bargain. *See Betco*, 876 F.3d at 310 (applying Wisconsin law) (holding that a plaintiff cannot succeed on a claim for breach of implied duty without evidence of bad-faith actions that injured or destroyed the other party’s ability to receive the benefits of the contract).

78. Even looking back with impermissible hindsight, WARF’s original assignment of relative value was fair. As a later-invented and separate patent from the ’497 compound patent family, the ’815 patent was dominated by the ’497 compound patent until March 2015. FOF

¶¶ 54, 147. The '815 patent did not delay entry of any generics and therefore failed to provide any longer exclusivity for Zemplar, even with its 2011 listing in the Orange Book and 2012 assertion in litigation. FOF ¶ 148.

79. The share of royalties WashU actually received over 18 years was about the same as its share of incremental income from the '815 patent. FOF ¶ 149. The present value of actual payments to WashU was about \$1.5 million. WashU's share of \$4.1 million in incremental income from the '815 patent was only \$1.2 million. As WARF's expert Carla Mulhern testified, this comparison validates WARF's blended approach and proves that it was fair. [Mulhern 1096:14-1097:19.]

### **3. The 2008 Stoveken Email Does Not Trigger an Implied Breach**

80. WashU argued for the first time at trial that any implied duty to revalue would be triggered by "an allegation of breach triggered by knowledge on WARF's part," which "would go back to 2008 in the Stoveken e-mail." [Jacobs 1149:8-18.]

81. WashU failed to present sufficient evidence, however, of how Mr. Stoveken's personal interpretation of the claims of the '815 patent and Zemplar's label could possibly trigger a breach. Mr. Stoveken is not a patent attorney, licensing expert, or a medical doctor, and never worked for Abbott. [Stoveken 518:2-7.] He had recently joined WARF and testified that he reviewed the Abbott portfolio to try to estimate the last expiring patent in the portfolio. [Stoveken 503:1-16, 500:12-501:3.] The '815 patent had already been licensed to Abbott for 10 years at the time of his email. Nothing changed as a result of the 2008 Stoveken email, nor should anything have changed. The fact that the '815 patent was later expiring was not "news" to anyone—later invented patents are later expiring. As Mr. Stoveken testified, the email was not shared with anyone at Abbott [Stoveken 512:2-7], and WashU does not allege any specific action by Abbott that resulted because of the email. The 2008 Stoveken email cannot constitute

evidence of a “bad faith” action that Wisconsin’s courts have recognized as a potential breach under Wisconsin’s implied covenant.<sup>20</sup> See COL ¶ 66.

## V. WARF ESTABLISHED A LACHES DEFENSE

### A. Legal Standard

82. “Laches is an equitable doctrine whereby a party that delays making a claim may lose its right to assert that claim. Laches is distinct from a statute of limitations and may be found where the statute of limitations has not yet run.” *Zizzo v. Lakeside Steel & Mfg. Co.*, 752 N.W.2d 889, 892 (Wis. Ct. App. 2008).

83. Laches requires that the defense prove that (1) the plaintiff unreasonably delayed in bringing the claim, (2) the defense lacked any knowledge that the plaintiff would assert the right on which the suit is based, and (3) the defense is prejudiced by the delay. *Schafer v. Wegner*, 254 N.W.2d 193, 196 (Wis. 1977) (citing *Schneider Fuel & Supply Co. v. W. Allis State Bank*, 236 N.W.2d 266, 272 (Wis. 1975)).

84. In *Schafer*, a twenty-year-old claim to furniture was barred by laches following a divorce judgment, even though the claim was within the statute of limitations. *Id.* The court found that the delay was unreasonable because the defendant had no knowledge that plaintiff

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<sup>20</sup> Likewise, the expert report of Robert Virgil [JX84] from the *Hospira* litigation on the legal construct of “commercial success” is not evidence that WARF’s assignment of relative value was made in bad faith or was unfair. *See Merck & Co. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1376-77 (Fed. Cir. 2005) (finding the evidence of commercial success of a later once-weekly dosing patent “weak” because “market entry by others was precluded” by another Merck patent covering the administration of the drug). Three patents were litigated in the *Hospira* litigation: the ’497 compound patent, Abbott’s U.S. Patent No. 6,136,799, and the ’815 patent. [JX63; JX271; JX272.] To rebut *Hospira*’s invalidity defenses, WARF and Abbott argued that all three of the patents provided a “nexus” to Zemplar®’s commercial success. *AbbVie Inc. v. Hospira, Inc.*, 71 F. Supp. 3d 477, 486-87 (D. Del. 2014); [JX84.005; JX85.0037-39.] *Hospira* did not challenge the commercial success of the ’497 compound patent [JX84.005], but did challenge the commercial success based on the ’815 patent as well as the propriety of Abbott’s late listing of the joint patent in the Orange Book. [JX353; JX507.006-7.]

would try to reclaim the furniture after 16 years of silence. *Id.* (finding “[a]fter the 1960 [divorce] order the record is barren of any steps taken by the appellant to have the furniture removed until this action was commenced in December of 1973”).

85. “There is no fixed rule as to the lapse of time necessary to bar a suitor in a court of equity. Each case must stand upon its own particular facts. Great lapse of time, if reasonably excused and without damage to the defendant, has been ignored; while slight delay, accompanied by circumstances of negligence, apparent acquiescence, or change of defendant’s position, has been held sufficient.” *Likens v. Likens*, 117 N.W. 799, 801 (Wis. 1908) (finding no sufficient excuse was shown to explain a delay of ten years for plaintiff to assert his claim against defendants); *see also Paulson v. Lutze*, No. 2015AP230-FT, 2015 WL 6133057, at \*2 (Wis. Ct. App. Oct. 20, 2015) (holding plaintiff’s claim was barred because of a five-year delay between plaintiff’s knowledge and disagreement of a conveyance of a deed and his challenge of its validity); *Ripco Credit Union v. Bukovic*, No. 2014AP2168-FT, 2015 WL 1637189, at \*6 (Wis. Ct. App. Apr. 14, 2015) (holding that a six-year delay was unreasonable where defendant did not show that he did not have a reasonable basis to know of his claim).

#### **B. WashU Unreasonably Delayed in Bringing Suit to the Prejudice of WARF**

86. Despite knowing in 2001 about WARF’s relative valuation of the ’815 patent, WashU did not object or otherwise contest WARF’s valuation until 2012. FOF ¶ 111. From 2001 until 2012, WARF had no way to know that WashU would assert a breach-of-contract case because WashU accepted and cashed every royalty check without question. FOF ¶ 104. WashU admits that it received no more information from WARF prior to filing this suit in 2013 than it received in 2001. FOF ¶ 116. Unlike the facts in *Schroeder v. Goth*, No. 03-C-0299-C, 2004 U.S. Dist. LEXIS 7649 (W.D. Wis. Apr. 28, 2004), WashU did not file suit within the six-year statute of limitations. *See id.* at \*3 (finding plaintiff brought suit over a year before the statute of

limitations would have run). Moreover, as discussed above, there is no evidence that WARF's April 2001 Letter to WashU was misleading such that WashU was somehow kept in the dark. Therefore, WashU has unreasonably delayed in bringing suit to the prejudice of WARF.

87. Because of WashU's lack of diligence, WARF has paid 20 percent of the licensing revenue it received from Abbott to 26 other inventors, in addition to WashU, based on the same relative valuation established in 1998 for the Abbott portfolio. [Gulbrandsen 634:4-635:11, 695:12-696:1; JX10.001; JX11.] Had WashU raised its objections prior to 2012, WARF would have had notice of a possible challenge to its valuation. WARF could have withheld payment of the royalties that WashU contends should be allocated to the '815 patent until WashU's valuation challenge was resolved, or even reappropriated the assigned relative value if necessary after resolution of the dispute instead of making payments over the past 14 years. *See Schafer*, 254 N.W.2d at 196 (finding evidence of economic prejudice sufficient to demonstrate prejudice, as a matter of law).

88. WashU has unreasonably delayed in bringing suit to the prejudice of WARF, and all of its claims should be barred.

## **VI. THERE ARE NO DAMAGES IN THIS CASE**

### **A. Legal Standard**

89. “[T]he burden rests on the [plaintiff] to prove by credible evidence to a reasonable certainty that damages were suffered and to establish at least to a reasonable probability the amount of these damages.” *Pleasure Time, Inc. v. Kuss*, 254 N.W.2d 463, 470 (Wis. 1977).

90. “Neither a court nor a jury as the trier of the facts can determine damages by speculation or guess work. The trier of the fact may make a reasonable estimate of the damage based on relevant data and evidence. . . . Damages must be proven with reasonable certainty.” *DeSombre v. Bickel*, 118 N.W.2d 868, 873 (Wis. 1963) (citation omitted).

**B. WARF's Incremental-Benefit Analysis Demonstrates WashU's Lack of Financial Injury**

91. Since there has been no breach, there are no damages. There is no evidence of financial injury to WashU. WARF's economic expert's incremental-benefit analysis established that WashU has already been paid more under WARF's blended payouts (\$1.5 million present value) than its share of the incremental royalties attributable to the '815 patent (\$1.2 million present value). *See FOF ¶ 149.*

92. WashU has not proven any damages with reasonable certainty or that they may be readily ascertained. *See FOF ¶¶ 151-158.*

93. WashU has no evidence of damages specifically resulting from an alleged breach of implied covenant of good faith and fair dealing, and there is no evidence of financial injury to WashU as it has already been paid more than its share of the incremental royalties attributable to the '815 patent. *See FOF ¶¶ 149-150.*

**C. WashU Is Not Entitled to Prejudgment Interest**

94. To the extent that this Court awards damages to WashU, WashU should not be entitled to prejudgment interest under Wisconsin law.

95. “Under Delaware choice of law provisions, the subject of prejudgment interest is governed by the substantive law of the state wherein the contract was performed.” *Mobilificio San Giacomo S.p.A. v. Stoffi*, No. C.A. 96-415-SLR, 1998 WL 125536, at \*11 (D. Del. Jan. 29, 1998); *see also Rose Hall, Ltd. v. Chase Manhattan Overseas Banking Corp.*, 566 F. Supp. 1558, 1574 (D. Del. 1983). Therefore, Wisconsin law also applies to the determination of prejudgment interest here.

96. Under Wisconsin law, “[p]reverdict interest is available when damages are fixed and determinable or may be measured according to a reasonably certain standard.” *Loehrke v.*

*Wanta Builders, Inc.*, 445 N.W.2d 717, 722 (Wis. Ct. App. 1989). “An amount is determinable when there is ‘a reasonably certain standard of measurement by the correct application of which one can ascertain the amount he owes.’” *Didion Milling, Inc. v. Agro Distrib., LLC*, No. 05-C-227, 2007 WL 702808, at \*18 (E.D. Wis. Mar. 2, 2007) (quoting *Wyandotte Chems. Corp. v. Royal Elec. Mfg. Co.*, 225 N.W.2d 648, 651 (Wis. 1975)). “If damages are determinable only by resolution of factual disputes, the amount is not fixed and determinable and therefore prejudgment interest is not appropriate.” *Id.*

97. In the context of a contract dispute, if the contract is ambiguous and, thus, the court is required to interpret the contract, prejudgment interest is not appropriate because “the dispute goes to the very method of calculating the amount owed.” *Teff v. Unity Health Plans Ins. Corp.*, 666 N.W.2d 38, 54 (Wis. Ct. App. 2003) (quoting *Jones v. Jenkins*, 277 N.W.2d 815, 821 (Wis. 1979)).

98. Here, WashU’s damages calculation for an alleged breach of contract is not fixed, determinable, or one that may be measured according to a reasonably certain standard. WashU contends that WARF had been underpaying WashU for “nearly a decade” [D.I. 145, Ex. 11 (WashU’s Proposed COL) ¶¶ 450, 457], and its economics expert has identified a range of compensatory damages based on different relative values that he contends should be awarded. As evidenced by the testimony at trial, the parties dispute not only whether WashU has suffered any damages, but also the methodology of determining damages owed, if any, and the timing of any damages under the implied covenant. See FOF ¶¶ 151-159.

99. As awarding damages here would require resolving numerous disputed factual issues, prejudgment interest is not appropriate. See *Loehrke*, 445 N.W.2d at 722 (prejudgment interest not appropriate where it could not be determined before the verdict how much was

actually owed on the contract); *Jones*, 277 N.W.2d at 821 (prejudgment interest not appropriate where the trial court took evidence of the parties' intent and had to construe a contingency fee agreement in order to determine the amount owed); *Teff*, 666 N.W.2d at 54-55 (prejudgment interest not appropriate where factual issues needed to be resolved in order to determine the amount of lost income); *Redprairie Corp. v. Warehouse*, No. 05-C-1072, 2008 WL 11343691, at \*2 (E.D. Wis. Aug. 25, 2008) (prejudgment interest not appropriate because, whether or not plaintiff suffered any damages and, if so, in what amount, were disputed material facts that required a jury trial to resolve).

## **VII. WARF ESTABLISHED AN ACCORD-AND-SATISFACTION DEFENSE**

### **A. Legal Standard**

100. "Under the common law rule of accord and satisfaction, if a check offered by the debtor as full payment for a disputed claim is cashed by the creditor, the creditor is deemed to have accepted the debtor's conditional offer of full payment . . . . In other words, the creditor's cashing the full payment check constitutes an accord and satisfaction which discharges the entire debt." *Flambeau Prods. Corp. v. Honeywell Info. Sys.*, 341 N.W.2d 655, 658 (Wis. 1984).

101. "Where the amount due is in dispute, and the debtor sends cash or [a] check for less than the amount claimed, . . . the cashing of the check is almost always held to be an acceptance of the offer operating as full satisfaction," even where the creditor objects to the amount paid. *Butler v. Kocisko*, 479 N.W.2d 208, 211 (Wis. Ct. App. 1991) (quoting 6 Arthur L. Corbin, *Corbin on Contracts* § 1279, at 127-29 (1962)). The creditor will be "bound by the terms of the offer as made when he cashed the check and retained the proceeds." *Id.* at 212; *see also Thomas v. Columbia Phonograph Co.*, 129 N.W. 522, 524 (Wis. 1911) ("The plaintiff could not accept the offer and avail himself of the funds without assenting to the condition upon which the offer was made.").

102. In order for the cashing of a check to constitute accord and satisfaction, two elements must exist. First, “there must be a good faith dispute about the debt,” and second, “the creditor must have reasonable notice that the check is intended to be in full satisfaction of the debt.” *Flambeau*, 341 N.W.2d at 663.

**B. WashU’s Cashing of Each Check Since 2012 Constitutes Acceptance of WARF’s Assignment of Relative Value**

103. WashU first raised a dispute with WARF’s valuation of the ’815 patent on December 24, 2012. [JX195.] Even after raising a dispute, WashU continued to cash the royalty checks sent in 2013-2017, which used the same relative value and calculation that WashU directly disputed. FOF ¶¶ 100-102, 104. WARF enclosed a memo with each check, signifying that the check represented a payment in full for the annual shared royalties under the 1998 assigned relative value. By the time the checks were cashed, there was clearly a good-faith dispute about the debt, and a standstill agreement was in place to protect WashU’s rights to file any future claims. Despite this, WashU cashed each royalty check after 2012.

104. WashU’s retention of the royalty payments binds them to the terms of each check, letter, and memo received from WARF. *See Kocisko*, 479 N.W.2d at 212 (“Because no circumstances justify [plaintiff]’s retention of the money, we conclude that he was bound by the terms of the offer as made when he cashed the check and retained the proceeds.”).

105. Therefore, WashU has accepted the allocated relative value even after 2012, and annually reaffirmed its acceptance.

**C. WARF Timely Disclosed Its Accord-and-Satisfaction Defense**

106. As explained in the pretrial order (D.I. 154 at 12-13), WARF has not waived its affirmative accord-and-satisfaction defense. The very first time WARF answered the complaint,

in accordance with the Court's amended scheduling order (D.I. 144), WARF plead the accord and satisfaction defense. D.I. 145.

107. Because WARF's timely filed a motion to dismiss all of WashU's claims, WARF's answer to the complaint was not previously due under the Federal Rules of Civil Procedure while fact discovery was ongoing. Fed. R. Civ. P. 12(a)(4)(A). WARF's affirmative defense of accord and satisfaction, however, was well known to WashU from the discovery that occurred in this case. From its Motion to Dismiss throughout discovery and summary judgment briefing, WARF has repeatedly asserted the facts supporting the affirmative defense of accord and satisfaction:

- WARF's Brief in Support of its Motion to Dismiss (D.I. 14) at 12: "WARF has continued to this day to make payments to WashU based on the relative value WARF assigned . . . . And until 2012, WashU accepted those payments without further inquiry, and without giving WARF any indication that WashU had additional questions or concerns."
- WARF's Brief in Support of its Motion for Summary Judgment (D.I. 97) at 7-8:

After this first royalty report and payment, WARF provided a royalty report along with a check annually to WashU, with letters sent in 1999, 2001 (twice), 2003 (twice), 2004, 2005, 2006, 2007, 2008, 2009, 2010, 2011, 2012, 2013, and 2014. (B2–B3; C196–C233.) Each of WARF's royalty calculations was based on the same relative value WARF assigned to the '815 patent in 1998, and in every case, the letters closed with an invitation for WashU to contact WARF if they had any questions concerning the report or payment. WashU accepted and deposited each of the royalty checks from 1998 to 2014. (D64-D71 at 208:15–235:9.)

- In its responses to WARF's requests for admissions, WashU has admitted that it has deposited the royalty checks received from WARF. [JX345.003.]

108. WashU has not established any prejudice from WARF's timely assertion of the defense; to the contrary, the underlying facts are uncontested and WashU has had fair notice of the defense, as well as ample and adequate opportunity to respond in discovery and in its summary judgment briefing and pretrial submissions, and it did in fact respond on the merits. *See Hassan v. U.S. Postal Serv.*, 842 F.2d 260, 263-64 (11th Cir. 1988) (holding that because plaintiff "had notice that the government planned to raise the issue at trial . . . , we cannot say that the government's argument unfairly surprised or prejudiced the plaintiff").

### **VIII. CONCLUSION**

109. For the reasons set forth above, WashU's breach-of-contract claims, which are based on WARF's allocation of relative value in 1998, should be dismissed as time-barred under Wisconsin's six-year statute of limitations and the equitable doctrine of laches. WashU has also failed to prove that WARF's assignment of relative value was not fair such that WARF breached the IIA either expressly or pursuant to the covenant of good faith and fair dealing. WARF has further established an accord-and-satisfaction defense to WashU's allegations of breach based on WashU's cashing of WARF's royalty checks from 2013 until 2017.

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